

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D. C. 20549**

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2007

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-23837

SurModics, Inc.

(Exact name of registrant as specified in its Charter)

MINNESOTA
(State of incorporation)

41-1356149
(I.R.S. Employer Identification No.)

9924 West 74th Street
Eden Prairie, Minnesota 55344
(Address of principal executive offices)

Registrant's telephone number, including area code: (952) 829-2700

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes No

The number of shares of the registrant's Common Stock, \$.05 par value per share, outstanding as of July 31, 2007 was 17,995,294.

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PART I. FINANCIAL INFORMATION

SURMODICS, INC.
Condensed Balance Sheets
(In thousands, except share data)

	June 30, 2007 (unaudited)	September 30, 2006
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 3,960	\$ 3,751
Short-term investments	42,343	55,062
Accounts receivable, net	30,460	14,493
Inventories	1,259	952
Deferred tax asset	496	435
Income tax receivable	483	—
Prepays and other	1,754	1,403
Total current assets	<u>80,755</u>	<u>76,096</u>
Property and equipment, net	11,447	11,686
Long-term investments	47,785	47,758
Deferred tax asset	3,268	4,883
Other assets, net	21,603	16,979
Total Assets	<u>\$ 164,858</u>	<u>\$ 157,402</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 1,013	\$ 963
Accrued liabilities	1,470	2,880
Accrued income taxes payable	—	1,910
Deferred revenue	3,654	2,236
Other current liabilities	1,000	1,000
Total current liabilities	<u>7,137</u>	<u>8,989</u>
Deferred revenue, less current portion	20,175	2,210
Other long-term liabilities	—	1,000
Total Liabilities	<u>27,312</u>	<u>12,199</u>
Commitments and contingencies (Note 11)		
Stockholders' Equity		
Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding	—	—
Common stock- \$.05 par value, 45,000,000 shares authorized; 17,979,280 and 18,830,455 shares issued and outstanding	899	942
Additional paid-in capital	68,728	96,281
Accumulated other comprehensive income (loss)	2,393	(293)
Retained earnings	65,526	48,273
Total Stockholders' Equity	<u>137,546</u>	<u>145,203</u>
Total Liabilities and Stockholders' Equity	<u>\$ 164,858</u>	<u>\$ 157,402</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

Item 1. Financial Statements

SURMODICS, INC.
Condensed Statements of Income
(In thousands, except per share data)
(unaudited)

	Three Months Ended June 30		Nine Months Ended June 30	
	2007	2006	2007	2006
Revenue				
Royalties and license fees	\$ 13,416	\$ 13,948	\$ 39,664	\$ 39,514
Product sales	2,947	2,659	9,054	7,914
Research and development	1,399	1,532	3,147	4,883
Total revenue	<u>17,762</u>	<u>18,139</u>	<u>51,865</u>	<u>52,311</u>
Operating costs and expenses				
Product	1,217	891	3,396	2,441
Research and development	6,200	5,281	17,124	14,935
Sales and marketing	343	348	989	1,052
General and administrative	2,484	2,156	6,644	6,887
Total operating costs and expenses	<u>10,244</u>	<u>8,676</u>	<u>28,153</u>	<u>25,315</u>
Income from operations	<u>7,518</u>	<u>9,463</u>	<u>23,712</u>	<u>26,996</u>
Other income				
Investment income	1,211	1,113	3,731	2,894
Impairment loss	—	—	—	(4,651)
Other loss	(10)	(11)	(29)	(112)
Other income (loss)	<u>1,201</u>	<u>1,102</u>	<u>3,702</u>	<u>(1,869)</u>
Income before income taxes	8,719	10,565	27,414	25,127
Income tax provision	<u>(3,132)</u>	<u>(4,207)</u>	<u>(10,161)</u>	<u>(11,087)</u>
Net income	<u>\$ 5,587</u>	<u>\$ 6,358</u>	<u>\$ 17,253</u>	<u>\$ 14,040</u>
Basic net income per share	\$ 0.31	\$ 0.34	\$ 0.95	\$ 0.76
Diluted net income per share	\$ 0.31	\$ 0.34	\$ 0.95	\$ 0.75
Weighted average shares outstanding				
Basic	17,815	18,570	18,116	18,494
Dilutive effect of outstanding stock options	153	155	133	187
Diluted	17,968	18,725	18,249	18,681

The accompanying notes are an integral part of these unaudited condensed financial statements.

SURMODICS, INC.
Condensed Statements of Cash Flows
(In thousands)
(unaudited)

	Nine months ended June 30,	
	2007	2006
Operating Activities		
Net income	\$ 17,253	\$ 14,040
Adjustments to reconcile net income to net cash provided by operating activities-		
Depreciation and amortization	2,923	2,726
Loss on equity method investment and sales of investments	29	112
Amortization of discount on investments	(1,354)	(941)
Noncash compensation	5,035	4,358
Tax benefit from exercise of stock options	—	(116)
Impairment loss	—	4,651
Deferred taxes	(106)	(758)
Other	—	24
Loss on disposals of property and equipment	370	83
Change in operating assets and liabilities:		
Accounts receivable	4,033	(866)
Inventories	(307)	(24)
Accounts payable and accrued liabilities	(701)	(789)
Income taxes	(2,393)	4,574
Deferred revenue	(683)	(120)
Prepays and other	(502)	120
Net cash provided by operating activities	<u>23,597</u>	<u>27,074</u>
Investing Activities		
Purchases of property and equipment	(2,054)	(5,300)
Proceeds from sales of property and equipment	36	0
Purchases of available-for-sale investments	(131,971)	(135,609)
Sales/maturities of available-for-sale investments	146,208	110,357
Purchase of licenses and patents	(1,224)	(906)
Purchase of equity in OctoPlus, Novocell and other	(2,147)	(160)
Repayment of notes receivable	395	—
Net cash provided by (used in) investing activities	<u>9,243</u>	<u>(31,618)</u>
Financing Activities		
Tax benefit from exercise of stock options	—	116
Issuance of common stock	2,399	2,377
Repurchase of common stock	(35,030)	—
Net cash (used in) provided by financing activities	<u>(32,631)</u>	<u>2,493</u>
Net change in cash and cash equivalents	209	(2,051)
Cash and Cash Equivalents		
Beginning of period	3,751	3,921
End of period	<u>\$ 3,960</u>	<u>\$ 1,870</u>
Cash paid for income taxes	\$ 12,606	\$ 7,365
Noncash transaction-acquisition of property, plant, and equipment on account	\$ 330	\$ 1,043
Accrual of deferred Merck license revenue	\$ 20,000	—

The accompanying notes are an integral part of these unaudited condensed financial statements.

SURMODICS, INC.
Notes to Condensed Financial Statements
Period Ended June 30, 2007
(Unaudited)

(1) Basis of Presentation

In the opinion of management, the accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and reflect all adjustments, consisting solely of normal recurring adjustments, needed to fairly present the financial results for the interim periods presented. These financial statements include some amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of earnings in the period in which the change in estimate is identified. The results of operations for the three month period ended June 30, 2007 are not necessarily indicative of the results that may be expected for the entire 2007 fiscal year.

In accordance with the rules and regulations of the United States Securities and Exchange Commission, the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited financial statements of the Company. These unaudited condensed financial statements should be read together with the audited financial statements for the year ended September 30, 2006, and footnotes thereto included in the Company's Form 10-K as filed with the United States Securities and Exchange Commission on December 14, 2006.

(2) New Accounting Pronouncements

On July 13, 2006, Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 48, Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109, was issued. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The new FASB standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for the Company in fiscal 2008. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition.

In September 2006, FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157 ("SFAS No. 157"), Fair Value Measurements. This statement establishes a consistent framework for measuring fair value and expands disclosures on fair value measurements. SFAS No. 157 is effective for the Company starting in fiscal 2008. We have not determined the impact, if any, the adoption of this statement will have on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities ("SFAS No. 159"). SFAS No. 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. SFAS No. 159 is effective for the Company in fiscal 2009. We are currently evaluating the impact of SFAS No. 159 on our consolidated financial position and results of operations.

(3) Other Assets

Other assets consist principally of investments in marketable securities, a note receivable and acquired patents. The balance in other assets increased primarily as a result of an additional investment in OctoPlus N.V. and the increased market value of OctoPlus during the year. In October 2006, we made an additional investment of \$1.9 million in OctoPlus, a company based in the Netherlands active in the development of pharmaceutical formulations incorporating novel biodegradable polymers. Also in October 2006, OctoPlus common stock began trading on an international exchange following an initial public offering of its common stock. With a readily determinable fair market value, the Company now treats the investment in OctoPlus as an available-for-sale investment rather than a cost method investment. Available-for-sale investments are reported at fair value with unrealized gains and losses excluded from operations and reported as a separate component of stockholders' equity, except for other-than-temporary impairments, which are reported as a charge to current operations and result in a new cost basis for the investment. Our investment in OctoPlus represents an ownership interest of less than 20%.

In September 2005, we entered into an agreement to sell a contract manufacturing facility and 27 acres of land located in Bloomington, Minnesota. The terms of the sale agreement included a \$100,000 cash down payment and a note receivable of \$6.9 million, which is collateralized by the property. The terms of the note call for monthly installment payments of principal and interest at 6% with the remaining amount due and payable in September 2010. The \$5.3 million balance in other assets represents the long-term portion due on the note.

On July 10, 2007, we made a \$3.5 million equity investment in Paragon Intellectual Properties, LLC and its wholly owned subsidiary Apollo Therapeutics, LLC. In addition to the equity investment, we entered into a licensing agreement with Apollo Therapeutics, LLC whereby we will provide coating technology. See Note 12.

The Company recorded amortization expense of \$443,000 and \$1.3 million for the three and nine months ended June 30, 2007, respectively. We expect to incur approximately \$1.8 million of amortization each year in fiscal years 2007 and 2008, \$503,000 in fiscal 2009, and \$85,000 in fiscal years 2010 through 2012. Management does not believe an other-than-temporary impairment existed as of June 30, 2007, with respect to its existing investments. Other assets consisted of the following:

<i>(in thousands)</i>	June 30, 2007	September 30, 2006
Abbott license	\$ 7,037	\$ 7,037
Note receivable (long-term portion)	5,280	5,635
Investment in Novocell	559	559
Investment in OctoPlus	10,331	4,095
Investment in ThermopectiX	1,185	1,000
Patents and other	2,051	2,262
Less-accumulated amortization	(4,840)	(3,609)
Other assets, net	<u>\$ 21,603</u>	<u>\$ 16,979</u>

(4) Accounts Receivable

Accounts receivable at June 30, 2007 includes a \$20 million up front licensing fee due from Merck & Co., Inc. ("Merck"). Merck paid the licensing fee on July 20, 2007. See Note 10.

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(5) Inventories

Inventories are stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead. Inventories consisted of the following components:

<i>(in thousands)</i>	June 30, 2007	September 30, 2006
Raw materials	\$ 642	\$ 512
Finished goods	617	440
	<u>\$ 1,259</u>	<u>\$ 952</u>

(6) Operating Segments

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance.

SurModics manages its business on the basis of the operating segments noted in the table below, which are composed of the Company's six business units. The three operating segments are aggregated into one reportable segment. The "Drug Delivery" operating segment contains: (1) the Drug Delivery business unit and (2) the Ophthalmology division. The "Hydrophilic and Other" operating segment consists of three business units: (1) Hydrophilic Technologies, (2) Regenerative Technologies, and (3) Orthopedics. The "In Vitro" operating segment contains the In Vitro Technologies (formerly Diagnostics and Drug Discovery) business unit. Each operating segment has similar economic characteristics, technology, manufacturing processes, customers, regulatory environments, and shared infrastructures. The Company manages its expenses on a company-wide basis, as many costs and activities are shared among the business units and a majority of the Company's employees reside in shared resource units. The focus of the business units is to provide solutions to customers and maximizing revenue over the long-term. The accounting policies for segment reporting are the same as for the Company as a whole. The table below presents revenue from the three operating segments.

<i>(in thousands)</i>	Three months ended June 30,		Nine months ended June 30,	
	2007	2006	2007	2006
Operating segment:				
Drug Delivery	\$ 5,772	\$ 8,647	\$ 18,607	\$ 25,580
Hydrophilic and Other	6,897	5,522	18,720	15,988
In Vitro	5,093	3,970	14,538	10,743
Total revenue	<u>\$ 17,762</u>	<u>\$ 18,139</u>	<u>\$ 51,865</u>	<u>\$ 52,311</u>

(7) Stock-based Compensation

Commencing October 1, 2005, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share Based Payment" ("SFAS 123(R)"), which requires all share-based payments, including grants of stock options, to be recognized in the income statement as an operating expense, based on their fair values, over the requisite service period. The Company recorded \$2.2 million and \$5.0 million of related compensation expense, before taxes, for the three and nine months ended June 30, 2007, respectively. The Company recorded \$1.6 million and \$4.4 million of related compensation expense, before taxes, for the three and nine months ended June 30, 2006, respectively.

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The Company uses the Black-Scholes option pricing model to determine the weighted average fair value of options. The weighted average fair value of options granted during the three month periods ended June 30, 2007 and 2006 were \$16.41 and \$14.37, respectively. The fair market value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for the three months ended June 30, 2007 and June 30, 2006, respectively: risk-free interest rates of 4.61% and 5.04%; expected lives of 5.0 years and 4.6 years; and expected volatility of 41% and 42%. The weighted average fair value of options granted during the nine month periods ended June 30, 2007 and 2006 were \$16.55 and \$17.55, respectively. The following weighted-average assumptions were used for the nine months ended June 30, 2007 and June 30, 2006, respectively: risk-free interest rates of 4.64% and 4.67%; expected lives of 5.7 years and 4.9 years; and expected volatility of 49% and 48%.

The Company's Incentive Stock Options ("ISO") are granted at a price of at least 100% of the fair market value of the Common Stock on the date of the grant or 110% with respect to optionees who own more than 10% of the total combined voting power of all classes of stock. Options generally expire in seven years or upon termination of employment and are exercisable at a rate of 20% per year commencing one year after the date of grant. Nonqualified stock options are also granted at fair market value on the date of grant. Options generally expire in 3 to 10 years and are exercisable at rates of 20% per year from the date of grant or 20% to 33% per year commencing one year after the date of grant.

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of Common Stock ("Restricted Stock"). The Restricted Stock will be released to the key employees if they are employed by the Company at the end of the vesting period. Compensation has been recognized for the estimated fair value of the 148,664 unvested common shares and is being charged to income over the vesting term. Stock compensation expense recognized related to these awards totaled \$292,000 and \$324,000 during the three month periods ended June 30, 2007 and 2006, respectively. Stock compensation expense recognized related to these awards totaled \$848,000 and \$648,000 during the nine month periods ended June 30, 2007 and 2006, respectively.

Performance Share Awards

The Company has entered into Performance Share agreements with certain key employees, covering the issuance of Common Stock ("Performance Shares"). The Performance Shares will vest upon the achievement of all or a portion of certain performance objectives which must be achieved during the performance period. Stock compensation expense related to the Performance Share awards expected to vest totaled \$667,000 and \$183,000 during the three month periods ended June 30, 2007 and 2006, respectively. Stock compensation expense related to these awards totaled \$805,000 and \$540,000 during the nine month periods ended June 30, 2007 and 2006, respectively.

1999 Employee Stock Purchase Plan

Under the 1999 Employee Stock Purchase Plan ("Stock Purchase Plan") the Company is authorized to issue up to 200,000 shares of Common Stock. All full-time and part-time employees can choose to have up to 10% of their annual compensation withheld to purchase the Company's Common Stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of June 30, 2007, there was approximately \$184,000 of employee contributions included in accrued liabilities in the accompanying balance sheets. Stock compensation

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expense recognized related to Stock Purchase Plan totaled \$38,000 and \$40,000 during the three month periods ended June 30, 2007 and 2006, respectively and totaled \$118,000 and \$123,000 during the nine month periods ended June 30, 2007 and 2006, respectively.

(8) Comprehensive Income

The components of comprehensive income are as follows:

<i>(in thousands)</i>	Three months ended June 30,		Nine months ended June 30,	
	2007	2006	2007	2006
Net income	\$ 5,587	\$ 6,358	\$ 17,253	\$ 14,040
Other comprehensive income:				
Unrealized holding gains (losses) on available-for-sale securities arising during the period, net of tax	(173)	(90)	2,668	(359)
Add reclassification adjustment for realized losses included in net income, net of tax	6	7	18	70
Other comprehensive income (loss)	(167)	(83)	2,686	(289)
Comprehensive income	\$ 5,420	\$ 6,275	\$ 19,939	\$ 13,751

(9) Share Repurchases

In September 2006, the Board of Directors of the Company authorized the repurchase of \$35 million and up to 1 million shares of SurModics common stock. In January 2007, the authorization was amended to provide for repurchases up to an aggregate cost not to exceed \$35 million without restriction as to the number of shares repurchased. During the nine months ended June 30, 2007, the Company repurchased a total of 1,007,752 shares for \$35 million at an average price of \$34.76 per share. By the end of second quarter of fiscal 2007, the Company had purchased all the shares authorized under the repurchase program approved in September 2006 and amended in January 2007.

(10) Arrangement with Merck & Co., Inc.

On June 27, 2007 the Company announced a license and research collaboration agreement with Merck. The agreement calls for SurModics and Merck to pursue the joint development and commercialization of SurModics' I-vation sustained drug delivery system with TA (Triamcinolone acetonide) and other products combining certain of Merck's proprietary drug compounds and the I-vation system for the treatment of serious retinal diseases. Under the terms of the agreement, Merck will lead and fund development and commercialization activities. SurModics received an up front licensing fee of \$20 million and will be eligible to receive up to an additional \$288 million in fees and development milestones. In addition Merck will reimburse SurModics for its development activities, and the Company will be responsible for the manufacture and supply of the jointly developed products. The Company will also receive royalties on product sales. The \$20 million up front license fee was reported in accounts receivable and deferred revenue as of June 30, 2007. The Company will recognize the revenue from the up-front license fee over the life of the Merck agreement. SurModics received the \$20 million license fee payment on July 20, 2007.

(11) Commitments and Contingencies

On May 22, 2007, the former Stockholders of InnoRx (the “Plaintiffs”) filed a declaratory judgment action (the “Declaratory Judgment”) in the U.S. District Court for the Southern District of Alabama against Michael Cooney, M.D. (“Dr. Cooney”) of New York, New York. In the litigation, the Plaintiffs are seeking a determination that Dr. Cooney was not a co-founder of InnoRx, and further that he was not an inventor of certain patent rights covering technology for delivering drugs to the eye, including certain patent rights exclusively licensed by the Johns Hopkins University to InnoRx (collectively, the “Patent Rights”), and now controlled by the Company as successor-in-interest to InnoRx pursuant to an agreement of merger between the Company and InnoRx made effective on January 18, 2005 (the “Merger Agreement”). The Company is not a party to the litigation.

On June 8, 2007, the Company was named as a defendant in litigation filed in the U.S. District Court for the District of Minnesota by Dr. Cooney. JHU and certain former shareholders of InnoRx, among others, were also named as defendants. The complaint alleges that Dr. Cooney was a co-founder of InnoRx and an inventor of subject matter claimed in the Patent Rights. The complaint seeks an order correcting inventorship, and certain unspecified damages (including punitive damages) based on claims of unjust enrichment, fraud, and breach of fiduciary duties. A trial has not yet been scheduled. Pursuant to the Merger Agreement, the Company has submitted a demand for indemnification of losses (including without limitation, damages, expenses and costs) incurred as a result of the litigation involving Dr. Cooney, including both the Alabama and Minnesota cases described above.

On June 18, 2007, the Company was named as an involuntary plaintiff in patent litigation between Abbott Laboratories (“Abbott”) and Church & Dwight, Inc. (“Church & Dwight”). In the litigation, Abbott is alleging that certain of Church & Dwight’s products utilizing lateral flow technology for diagnostic purposes infringe certain of the Company’s patents that have been exclusively licensed to Abbott under the terms of a license agreement between the Company and Abbott dated May 30, 1989, as amended and restated (the “License Agreement”). The suit was filed in the U.S. District Court for the Northern District of Illinois seeking a finding of infringement, monetary damages and injunctive relief. Pursuant to the terms of the License Agreement, Abbott is responsible for reimbursing the Company for at least a portion of its costs and fees incurred in connection with the suit. A trial has not yet been scheduled.

(12) Subsequent Events

On July 10, 2007 the Company announced its equity investment in Paragon Intellectual Properties, LLC (“Paragon”) and an equity investment in Apollo Therapeutics, LLC (“Apollo”), a Paragon subsidiary. The Paragon and Apollo investments totaled \$3.5 million. The arrangement calls for SurModics to invest additional equity totaling \$2.5 million upon successful completion of specified development milestones. The investment in Paragon represents an ownership interest of less than 20% and the investment in Apollo represents an ownership interest of less than 20%.

On July 31, 2007 the Company entered into a stock purchase agreement with Southern Research Institute whereby it acquired 100% of the capital stock of Brookwood Pharmaceuticals, Inc. (“Brookwood”) held by Southern Research Institute for \$40 million in cash on the closing date and up to an additional \$22 million in cash upon the successful achievement of specified milestones. Brookwood is a drug delivery company based in Birmingham, Alabama that provides proprietary polymer based technologies to companies developing pharmaceutical products. The Company is evaluating the purchase price allocation and expects to write off a portion of the purchase price as purchased research and development in its fourth quarter of fiscal 2007. Brookwood, a wholly owned subsidiary of SurModics, will operate as a separate business unit.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Overview

SurModics is a leading provider of surface modification and drug delivery technologies to the healthcare industry. The Company is organized into three operating segments composed of six technology-centered and industry-focused business units. The “Drug Delivery” operating segment contains: (1) the Drug Delivery business unit, which is responsible for technologies dedicated to site-specific delivery of drugs, and (2) the Ophthalmology division, which is dedicated to the advancement of treatments for eye diseases, such as age-related macular degeneration (AMD) and diabetic macular edema (DME), two of the leading causes of blindness. The “Hydrophilic and Other” operating segment consists of three business units: (1) Hydrophilic Technologies business unit, which focuses on enhancing medical devices with advanced lubricious coatings that facilitate their placement and maneuverability in the body; (2) Regenerative Technologies business unit, which is developing platforms intended to augment or replace tissue/organ function (e.g., cell encapsulation applications), or to modify medical devices to facilitate tissue/organ recovery through natural repair mechanisms (e.g., biocompatible or prohealing coatings); and (3) Orthopedics business unit, which is committed to innovative solutions for orthopedics patients using proven SurModics technologies, and creating new technology solutions to existing patient care gaps in the orthopedics field. The “In Vitro” operating segment contains the In Vitro Technologies (formerly Diagnostics and Drug Discovery) business unit, which includes our genomics slide technologies, our stabilization and antigen products for immunoassay diagnostic tests, our in vitro diagnostic format technology and our synthetic cell culture products.

Revenue in each of our operating segments is derived from three primary sources: (1) royalties and license fees from licensing our patented surface modification and drug delivery technologies and in vitro diagnostic formats to customers; the vast majority (typically in excess of 90%) of revenue in the “royalties and license fees” category is in the form of royalties; (2) the sale of reagent chemicals to licensees of our technologies, stabilization products to the diagnostics industry and coated glass slides to the genomics market; and (3) research and development fees generated on customer projects. Revenue should be expected to fluctuate from quarter to quarter depending on, among other factors: our customers’ success in selling products incorporating our technologies; the timing of introductions of coated products by customers; the timing of introductions of products that compete with our customers’ products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized; the value of reagent chemicals and other products sold to licensees; and the timing of future acquisitions we complete, if any.

For financial accounting and reporting purposes, we treat our three operating segments as one reportable segment. We made this determination because our operating segments currently share the same facilities; a significant percentage of our employees provide support services (including research and development) to each operating segment; technology and products from each operating segment are marketed to the same or similar customers; each operating segment uses the same sales and marketing resources; and each operating segment operates in the same regulatory environment.

Critical Accounting Policies

Critical accounting policies are those policies that require the application of management’s most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently sensitive to result in materially different results under different assumptions and conditions. For a detailed description of our critical accounting policies, see the notes to the financial statements included in our Annual Report on Form 10-K for the year ended September 30, 2006.

Results of Operations**Three Months Ended June 30, 2007 and 2006**

(in thousands)	2007	2006	Increase/ (Decrease)	% Increase/ (Decrease)
Revenue:				
Drug Delivery	\$ 5,772	\$ 8,647	(\$2,875)	(33%)
Hydrophilic and Other	6,897	5,522	1,375	25%
In Vitro	5,093	3,970	1,123	28%
Total revenue	<u>\$ 17,762</u>	<u>\$ 18,139</u>	<u>(\$377)</u>	<u>(2%)</u>

Revenue. Third quarter revenue was \$17.8 million, a decrease of \$377,000, or 2%, compared with the same period in fiscal 2006. Substantial growth in our Hydrophilic and Other and In Vitro operating segments was offset by a 33% decrease in Drug Delivery segment revenue. Results for each of our three operating segments are detailed in the table above and further explained in the narrative below.

Drug Delivery. Revenue in the Drug Delivery segment decreased 33% to \$5.8 million for the three-month period ended June 30, 2007, compared with \$8.6 million for the prior year period. Nearly all of the decrease is a result of lower royalties and license fees when compared with the prior year period. Drug Delivery derives a substantial majority of its revenue through licensing and product sales to Cordis Corporation, a Johnson & Johnson company, on its CYPHER® Sirolimus-eluting Coronary Stent. CYPHER® is a trademark of Cordis Corporation. The CYPHER® stent incorporates a proprietary SurModics polymer coating that delivers a therapeutic drug designed to reduce the occurrence of restenosis in coronary artery lesions. The decrease in Drug Delivery revenue reflects lower royalty revenue and reagent revenue (as a result of lower CYPHER® sales) and less research and development work performed for Cordis. Excluding Cordis activities, research and development revenue decreased 6% compared with the prior year period as a result of reduced activity with ophthalmology and other drug delivery customers.

The CYPHER® stent, from which we derive a substantial majority of our Drug Delivery revenue, faces continuing competition from Boston Scientific Corporation's Taxus drug-eluting stent, which is sold within and outside the U.S., and stents from Medtronic, Abbott Vascular, and others sold outside the U.S. In addition, several drug-eluting stents from others are expected to be approved in the U.S. over the next two years. These stents (in addition to bare metal stents) compete or will compete directly with the CYPHER® stent. Further, drug-eluting stent sales have been adversely affected by recent concerns over stent safety. Therefore, future Drug Delivery royalty and reagent sales revenue could decrease because of lower CYPHER® stent sales as a result of this ongoing and expected future competition and overall market contraction. We anticipate that quarterly royalty revenue from the CYPHER® stent may decrease for the remainder of fiscal 2007 and beyond as the various marketers of drug-eluting stents continue competing in the marketplace and as others enter the marketplace. Management expects royalties from the CYPHER® stent to continue to constitute a significant portion of our revenue in fiscal 2007. However, whether and the extent to which royalties from the CYPHER® stent continue to constitute a significant source of revenue is subject to a number of risks,

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including intellectual property litigation generally, and specifically the damages, settlements and mutual agreements that may result from various infringement suits between Boston Scientific and Cordis in which each has been found to have violated certain intellectual property rights of the other.

Hydrophilic and Other. Revenue in the Hydrophilic and Other segment increased 25% to \$6.9 million compared with the third quarter of fiscal 2006, primarily as a result of 29% growth in royalties and license fees and a 50% increase in reagent sales. In contrast to our Drug Delivery segment, where a significant percentage of revenue is attributable to Cordis, there are several dozen licensees and an even larger number of coated products generating royalties in our Hydrophilic and Other segment. Partially offsetting the increase in royalties and license fees and reagent sales was a 23% decrease in research and development revenue. Much of the research and development revenue earned in the Hydrophilic and Other segment is related to small-scale interim coating services we provide to some of our customers as they transition to coating their products with our technology in their own manufacturing facilities. Some of our customers, who had contributed significantly to research and development revenue in the prior year period, have transitioned to in-house coating. Accordingly, we performed less of this service in the third quarter of fiscal 2007, resulting in the decrease in research and development revenue. For this same reason, we anticipate research and development revenue within this segment will continue to decrease when compared to prior year comparable periods for the remainder of fiscal 2007. We believe royalty and license fee revenue will continue to increase for the remainder of fiscal 2007 when compared to prior year comparable periods, though not necessarily at the same rate experienced in the third quarter of fiscal 2007. It is unlikely that fourth quarter fiscal 2007 reagent sales, when compared to prior year comparable periods, will grow at the rate experienced in the third quarter of fiscal 2007.

In Vitro. Revenue in the In Vitro segment (formerly Diagnostics) increased 28% to \$5.1 million compared with the prior year period. A majority of the increase was attributable to a 44% increase in royalties and license fees compared with the same period in fiscal 2006. It is unlikely that fourth quarter fiscal 2007 In Vitro royalties and license fees, when compared with prior year comparable periods, will grow at the rate experienced in the third quarter of fiscal 2007.

Product sales in the In Vitro segment increased approximately 2% compared with the prior year. Product sales include genomics slides, stabilization products and recently launched recombinant autoimmune antigens (both stabilization products and antigens are used by diagnostic kit manufacturers in immunoassay diagnostic tests). However, when current period sales of antigens are excluded (prior year results do not include any antigen sales, as distribution of these products began in the fourth quarter of fiscal 2006) product sales decreased approximately 16%. We expect product sales in the In Vitro segment to be higher on a sequential basis in the final quarter of fiscal 2007. The In Vitro segment derives a significant percentage of its revenue from Abbott Laboratories and GE Healthcare. On January 18, 2007, Abbott announced an agreement to sell its core laboratory diagnostics business to GE. On July 11, 2007, Abbott announced that it and GE mutually agreed to terminate the sale agreement. We do not expect the termination of this transaction to have a material impact on future In Vitro operating segment results.

Product costs. Product costs were \$1.2 million for the third quarter of fiscal 2007, a 37% increase from \$891,000 in the third quarter of fiscal 2006. Overall product margins averaged 59%, compared with 66% for the comparable period last year. The decrease in product margins reflects the mix of products sold in the period (some of our stabilization and antigen products and genomics slides carry lower margins than our reagent products) and higher depreciation costs on the recently-constructed manufacturing space at our Eden Prairie facility. We anticipate that product margins will continue to be lower on a year-over-year basis throughout fiscal 2007 compared with prior year results as a result of recent trends in the mix of products sold.

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Research and development expenses. Research and development expenses were \$6.2 million in the third quarter of fiscal 2007, an increase of 17% compared with the same period in fiscal 2006. The increase reflects higher personnel costs and an approximate \$600,000 increase in stock based compensation paid to employees as a result of executing the Merck license. In addition, a \$353,000 loss was recorded on the cancellation of a technology license.

Sales and marketing expenses. Sales and marketing expenses were \$343,000 for the third quarter of fiscal 2007, a 1% decrease from the prior year period. We expect sales and marketing expenses to increase modestly on a year-over-year basis for the remainder of fiscal 2007.

General and administrative expenses. General and administrative expenses were \$2.5 million for the third quarter of fiscal 2007, a 15% increase compared with \$2.2 million in same period of fiscal 2006. The increase reflects increased legal and professional fees. General and administrative expenses will likely increase modestly in the fourth quarter of fiscal 2007.

Other income, net. Other income was \$1.2 million in the third quarter of fiscal 2007, an increase of 9% compared with \$1.1 million in the same period of fiscal 2006, reflecting higher levels of investable cash and higher yields generated from our investment portfolio.

Income tax expense. The Company's income tax provision was \$3.1 million in the third quarter of fiscal 2007, compared with \$4.2 million in the same period of fiscal 2006, resulting in an effective tax rate of 35.9% for the third quarter of fiscal 2007, compared with 39.8% for the same period last year. Current period results include a benefit from the release of certain tax reserves related to expiring statutes of limitations.

Nine Months Ended June 30, 2007 and 2006

<i>(in thousands)</i>	<u>2007</u>	<u>2006</u>	<u>Increase</u>	<u>% Increase</u>
Revenue:				
Drug Delivery	\$ 18,607	\$ 25,580	(\$6,973)	(27%)
Hydrophilic and Other	18,720	15,988	2,732	17%
In Vitro	14,538	10,743	3,795	35%
Total revenue	<u>\$ 51,865</u>	<u>\$ 52,311</u>	<u>(\$447)</u>	<u>(1%)</u>

Revenue. Total revenue was \$51.9 million for the first nine months of fiscal 2007, a decrease of \$447,000, or 1%, compared with the same period of fiscal 2006. A significant decrease in Drug Delivery segment revenue, primarily as a result of lower CYPHER® stent royalties, offset strong revenue growth in the Hydrophilic and Other and In Vitro segments.

Drug Delivery. Drug Delivery revenue decreased 27% to \$18.6 million through the third quarter of fiscal 2007, compared with \$25.6 million for the same period last year. The decrease reflects lower revenue in all three revenue sources: royalties and license fees, product sales, and research and development revenue as a result of lower CYPHER® sales and less research and development work performed for Cordis as described above.

Hydrophilic and Other. Hydrophilic and Other revenue increased 17% to \$18.7 million for the first nine months of fiscal 2007, driven principally by increased royalties and reagent sales. Partially offsetting the increase in royalties and reagent sales was a decrease in research and development revenue as a result of less interim contract coating work performed for certain customers as previously described.

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In Vitro. In Vitro revenue increased 35% to \$14.5 million compared with \$10.7 million for the same period last year. Approximately \$2.8 million of the increase is a result of higher royalties and license fees, a portion of which was a settlement related to past due royalties. The balance of the increase reflects the 28% growth in sales of genomics slides, stabilization and antigen product sales.

Product costs. Product costs were \$3.4 million for the nine months ended June 30, 2007, a 39% increase from \$2.4 million last year. Overall product margins averaged 62% compared with 69% for the comparable period last year. The margin decrease is primarily attributable to a higher mix of genomics slides, and stabilization and antigen products, which carry lower margins than reagents.

Research and development expenses. Research and development expenses were \$17.1 million for the first nine months of fiscal 2007, an increase of 15% compared with the same period in fiscal 2006. Approximately \$600,000 of the increase reflects higher costs associated with the clinical trial on our I-IVT intravitreal implant in our Ophthalmology division. The balance of the increase is a result of higher compensation and development expenses in all of our business segments.

Sales and marketing expenses. Sales and marketing expenses were \$989,000 for the nine months ending June 30, 2007, a 6% decrease from the same period of the prior year.

General and administrative expenses. General and administrative expenses were \$6.6 million for the first nine months of fiscal 2007, a 4% decrease compared with the same period in fiscal 2006. The decrease primarily reflects the cost savings realized since we exited our contract manufacturing facility in Bloomington in April 2006 and reduced professional fees.

Other income, net. Other income was \$3.7 million for the first nine months of fiscal 2007, compared with a loss of \$1.9 million in the same period last year. The prior year loss was primarily a result of the \$4.7 million impairment loss recorded on our investment in Novocell in the second quarter of fiscal 2006. Income from investments was \$3.7 million through the third quarter of fiscal 2007, an increase of \$837,000, compared with \$2.9 million for the same period of fiscal 2006, reflecting higher levels of investable cash and higher yields generated from our investment portfolio.

Income tax expense. The Company's income tax provision was \$10.2 million for the first nine months of fiscal 2007 compared with \$11.1 million in the same period of fiscal 2006. The effective tax rate for the first nine months of fiscal 2007 was 37.1%, compared with 37.2% for the same period last year (excluding the impact of the \$4.7 million impairment loss). Without excluding the impact of the impairment loss recorded in the first nine months of fiscal 2006, the effective tax rate for such period was 44.1%.

Liquidity and Capital Resources

As of June 30, 2007, the Company had working capital of \$73.6 million and cash, cash equivalents and investments totaling \$94.1 million. The Company's investments principally consist of U.S. government and government agency obligations and investment grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. The Company's policy requires that no more than 5% of investments be held in any one credit issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while meeting or exceeding a benchmark (Merrill Lynch 1-3 Year Government-Corporate Index) total rate of return. Management plans to continue to direct its investment advisors to manage the Company's investments primarily for the safety of principal for the foreseeable future as it assesses other investment opportunities and uses of its investments. We had positive cash flows from operating activities of approximately \$23.6 million in the first nine months of fiscal 2007, compared with \$27.1 million in the first nine months of fiscal 2006. On July 20, 2007, the Company received the \$20 million up front licensing fee due from Merck. See Note 4 and Note 10.

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We conduct a significant majority of our operations at our Eden Prairie, Minnesota, headquarters. In addition to our Eden Prairie location, we lease approximately 3,000 square feet of commercial office space in Irvine, California, where our Ophthalmology division conducts a portion of its operations.

In January 2005, we entered into a merger agreement whereby SurModics acquired all of the assets of InnoRx, Inc. by paying approximately \$4.1 million in cash and issuing 600,064 shares of SurModics common stock to InnoRx stockholders. In July 2005, we issued 60,002 shares of SurModics' common stock to the shareholders of InnoRx upon the successful completion of the first milestone involving the InnoRx technology acquired in the purchase of InnoRx. In March 2006, we issued an additional 60,007 shares as a result of completion of the second milestone. The 60,007 shares are held in escrow pending possible indemnification per the merger agreement. Upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction, we will be required to issue up to approximately 480,060 additional shares of our common stock to the stockholders of InnoRx.

In September 2004, we made a commitment to purchase for \$7 million certain additional sublicense rights and the accompanying future royalty revenue streams under certain sublicenses through an amendment to our diagnostic format patent license with Abbott Laboratories. Prior to such amendment, we were receiving only a portion of the royalties under such sublicenses. The first \$5 million installment was paid in November 2004. We made an additional \$1 million installment payment in June 2007. The remaining \$1 million installment is reflected in other current liabilities at June 30, 2007.

In September 2006, our Board of Directors authorized the repurchase of up to \$35 million and up to 1 million shares of the Company's stock. In November 2006, the Company entered into a Rule 10b5-1 agreement and purchased \$17.5 million of the \$35 million authorized at an average price of \$32.87 per share. In January 2007, the Board of Directors approved an amendment to the share repurchase program to authorize the Company to repurchase up to \$35 million of the Company's stock without restriction as to the total number of shares being repurchased. Pursuant to the amended share repurchase program, the Company entered into a Rule 10b5-1 agreement in January 2007 and during the second quarter of fiscal 2007 purchased the remaining \$17.5 million of the \$35 million repurchase authorization at an average price of \$36.88 per share. In total, the Company repurchased 1,007,752 shares for \$35.0 million at an average price of \$34.76 per share.

On July 10, 2007 we announced the Company's equity investment in Paragon Intellectual Properties, LLC ("Paragon") and an equity investment in Apollo Therapeutics, LLC ("Apollo"), a Paragon subsidiary. The Paragon and Apollo investments totaled \$3.5 million. The arrangement calls for the SurModics to invest additional equity totaling \$2.5 million upon successful completion of specified development milestones. Our investment in Paragon represents an ownership interest of less than 20% and the investment in Apollo represents an ownership interest of less than 20%. See Note 12.

On July 31, 2007 SurModics entered into a stock purchase agreement with Southern Research Institute whereby it acquired 100% of the capital stock of Brookwood Pharmaceuticals, Inc. ("Brookwood") for \$40 million in cash on the closing date and up to an additional \$22 million in cash upon the successful achievement of specified milestones. Brookwood is a drug delivery company based in Birmingham, Alabama that provides proprietary polymer based technologies to companies developing pharmaceutical products. See Note 12.

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As of June 30, 2007, we had no debt, nor did we have any credit agreements. We believe that our existing capital resources will be adequate to fund our operations and material commitments into the foreseeable future.

As of June 30, 2007, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

Certain information regarding the effective tax rate in this Quarterly Report on Form 10-Q may be considered non-GAAP financial information as contemplated by Regulation G. The non-GAAP measure excluded the impact of an impairment loss recorded in the second quarter of 2006. The Company no longer provides non-GAAP financial measures for the current period, but believes that providing this non-GAAP financial measure for the prior period is still useful to investors because it provides a basis for comparison of the Company's financial condition and results of operations between quarters, which comparison is not influenced by changes in its effective tax rate. Management also uses such financial measures internally to monitor performance of the business. The potential non-GAAP financial measures should be considered in addition to, and not a substitute for, financial measures in accordance with GAAP.

Forward-Looking Statements

Certain statements contained in this report and other written and oral statements made from time to time by the Company do not relate strictly to historical or current facts. As such, they are considered "forward-looking statements" that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar words or expressions. Any statement that is not an historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. The Company's forward-looking statements generally relate to its growth strategy, financial results, product development programs, sales efforts, sufficiency of capital resources, and the impact of the Cordis agreement and other significant customer agreements. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the Company's forward-looking statements, such factors include, among others: (i) the Company's significant dependence upon Cordis, which causes our financial results and stock price to be subject to factors affecting Cordis and its Cypher stent program, including among others, the rate of market penetration by Cordis, the timing of market introduction of competing products, product safety or efficacy concerns and intellectual property litigation generally and specifically the litigation involving Boston Scientific Scimed, Inc. and Cordis in the U.S. District Court for the District of Delaware in which each was reported in June and July 2005 to have been found to have infringed the patent rights of the other; (ii) frequent intellectual property litigation in the medical device industry that may directly or indirectly adversely affect our customers' ability to market their products incorporating our technologies; (iii) our ability to protect our own intellectual property; (iv) healthcare reform efforts and reimbursement rates for medical device products that may adversely affect our customers' ability to cost effectively market and sell devices incorporating our technologies; (v) the Company's ability to attract new licensees and to enter into agreements for additional product

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applications with existing licensees, the willingness of potential licensees to sign license agreements under the terms offered by the Company, and the Company's ability to maintain satisfactory relationships with its licensees; (vi) the Company's ability to increase the number of market segments and applications that use its coating technologies through its sales and marketing and research and development efforts; (vii) the Company's ability to facilitate through strategic investment and research and development support the creation of new medical device market segments and applications that incorporate its coating technologies; (viii) market acceptance of products sold by customers incorporating our technologies and the timing of new product introductions by licensees; (ix) market acceptance of products sold by customers' competitors and the timing and pricing of new product introductions by customers' competitors; (x) the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances, which may result in lost market opportunities or postpone or preclude product commercialization by licensees; (xi) efficacy or safety concerns with respect to products marketed by us and our licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales; (xii) the ability to secure raw materials for reagents the Company sells; (xiii) the Company's ability to manage successfully clinical trials and related foreign and domestic regulatory processes for the I-vation™ intravitreal implant or other acquired products from InnoRx under development by the Company's ophthalmology division, whether delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances postpone or preclude product commercialization of the intravitreal implant or other acquired products, and whether the intravitreal implant and any other acquired products remain viable commercial prospects; (xiv) product liability claims not covered by insurance; (xv) the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors; (xvi) the trend of consolidation in the medical device industry, resulting in more significant, complex and long term contracts than in the past and potentially greater pricing pressures; (xvii) the Company's ability to identify suitable businesses to acquire or with whom to form strategic relationships to expand its technology development and commercialization, its ability to successfully integrate the operations of companies it may acquire from time to time and its ability to create synergies from acquisitions and other strategic relationships; (xviii) the Company's ability to successfully internally perform certain product development activities and governmental and regulatory compliance activities with respect to acquired technology, including InnoRx technology, which activities the Company has not previously undertaken in any significant manner; (xix) the Company's ability to successfully perform and earn milestone payments related to contractual milestone criteria in general and specifically the \$288 million in fees and development milestones in the Merck agreement; (xx) economic and other factors over which the Company has no control, including changes in inflation and consumer confidence; (xxi) acts of God or terrorism which impact the Company's personnel or facilities; and (xxii) other factors described in the "Risk Factors" and other sections of SurModics' Annual Report on Form 10-K, which you are encouraged to read carefully. Many of these factors are outside the control and knowledge of the Company and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon the Company's forward-looking information and to consult any further disclosures by the Company on this subject in its filings with the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. The Company's investments principally consist of U.S. government and government agency obligations and investment-grade, interest-bearing corporate debt securities with varying maturity dates, the majority of which are five years or less. Because of the credit criteria of the Company's investment policies, the primary market risk associated with these investments is interest rate risk. SurModics does not use

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derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. A one percentage point increase in interest rates would result in an approximate \$1.4 million decrease in the fair value of the Company's available-for-sale securities as of June 30, 2007, but no material impact on the results of operations or cash flows. Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

Although we conduct business in foreign countries, our international operations consist primarily of sales of reagent and stabilization chemicals. Additionally, all sales transactions are denominated in U.S. dollars. Accordingly, we do not expect to be subject to material foreign currency risk with respect to future costs or cash flows from our foreign sales. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company conducted an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer regarding the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rule 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective to ensure that information that is required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the rules of the Securities and Exchange Commission.

Changes in Internal Controls

There were no changes in the Company's internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

On May 22, 2007, the former Stockholders of InnoRx (the "Plaintiffs") filed a declaratory judgment action (the "Declaratory Judgment") in the U.S. District Court for the Southern District of Alabama against Michael Cooney, M.D. ("Dr. Cooney") of New York, New York. In the litigation, the Plaintiffs are seeking a determination that Dr. Cooney was not a co-founder of InnoRx, and further that he was not an inventor of certain patent rights covering technology for delivering drugs to the eye, including certain patent rights exclusively licensed by the Johns Hopkins University to InnoRx (collectively, the "Patent Rights"), and now controlled by the Company as successor-in-interest to InnoRx pursuant to an agreement of merger between the Company and InnoRx made effective on January 18, 2005 (the "Merger Agreement"). The Company is not a party to the litigation.

On June 8, 2007, the Company was named as a defendant in litigation filed in the U.S. District Court for the District of Minnesota by Dr. Cooney. JHU and certain former shareholders of InnoRx, among others, were also named as defendants. The complaint alleges that Dr. Cooney was a co-founder of InnoRx and an inventor of subject matter claimed in the Patent Rights. The complaint seeks an order correcting inventorship, and certain unspecified damages (including punitive damages) based on claims of unjust enrichment, fraud, and breach of fiduciary duties. A trial has not yet been scheduled. Pursuant to the Merger Agreement, the Company has submitted a demand for indemnification of losses (including without limitation, damages, expenses and costs) incurred as a result of the litigation involving Dr. Cooney, including both the Alabama and Minnesota cases described above.

On June 18, 2007, the Company was named as an involuntary plaintiff in patent litigation between Abbott Laboratories ("Abbott") and Church & Dwight, Inc. ("Church & Dwight"). In the litigation, Abbott is alleging that certain of Church & Dwight's products utilizing lateral flow technology for diagnostic purposes infringe certain of the Company's patents that have been exclusively licensed to Abbott under the terms of a license agreement between the Company and Abbott dated May 30, 1989, as amended and restated (the "License Agreement"). The suit was filed in the U.S. District Court for the Northern District of Illinois seeking a finding of infringement, monetary damages and injunctive relief. Pursuant to the terms of the License Agreement, Abbott is responsible for reimbursing the Company for at least a portion of its costs and fees incurred in connection with the suit. A trial has not yet been scheduled.

Item 1A. Risk Factors.

There have been no material changes from risk factors as previously disclosed in the Company's Form 10-K for the fiscal year ended September 30, 2006 in response to Item 1A to Part I of Form 10-K.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

The following table presents information with respect to purchases of common stock of the Company made during the three months ended June 30, 2007, by the Company or on behalf of the Company or any “affiliated purchaser” of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

Period	(a) Total Number of Shares Purchased(1)	(b) Average Price Paid Per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
4/01/07 - 4/30/07	1,537	\$39.94	NA	NA
5/01/07 - 5/31/07	0	NA	NA	NA
6/01/07 - 6/30/07	5,296	\$49.42	NA	NA
Total	6,833	\$47.29		

- (1) All of the Shares were repurchased by the Company to pay the exercise price and/or to satisfy tax withholding obligations in connection with so-called “stock swap exercises” of employee stock options issued to employees.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Submission of Matters to a Vote of Security Holders.

None

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibits –

- 10.1+ Exclusive License and Research Collaboration Agreement with Merck & Co., Inc. dated June 26, 2007
- 10.2+ Supply Agreement with Merck & Co., Inc. dated June 26, 2007
- 31.1** Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
- 31.2** Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
- 32.1** Certification of Chief Executive Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002
- 32.2** Certification of Chief Financial Officer Pursuant to Section 906 of Sarbanes-Oxley Act of 2002

+ Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and provided separately to the Securities and Exchange Commission.

** Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SurModics, Inc.

August 9, 2007

By: /s/ Philip D. Ankeny
Philip D. Ankeny
Chief Financial Officer

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-Q
For the Quarter Ended June 30, 2007

SURMODICS, INC.

<u>Exhibit</u>	<u>Description</u>
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+ Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and provided separately to the Securities and Exchange Commission.

** Filed herewith.

EXCLUSIVE LICENSE AND RESEARCH COLLABORATION AGREEMENT
by and between
MERCK & CO., INC.
and
SURMODICS, INC.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

EXCLUSIVE LICENSE AND RESEARCH COLLABORATION AGREEMENT

THIS AGREEMENT (this “**Agreement**”) is effective as of June 26, 2007 (the “**Effective Date**”) and is entered into by and between Merck & Co., Inc., a corporation organized and existing under the laws of New Jersey (“**Merck**”) and SurModics, Inc., a corporation organized and existing under the laws of Minnesota (“**SurModics**”).

RECITALS:

WHEREAS, SurModics has developed SurModics Know-How (as hereinafter defined) and has SurModics Patent Rights (as hereinafter defined) relating to its I-vation Platform (as hereinafter defined);

WHEREAS, Merck and SurModics desire to enter into a research collaboration to develop the I-vation Platform for use with a certain steroid and with Merck’s pharmaceutical and biological products upon the terms and conditions set forth herein;

WHEREAS, Merck desires to obtain a license under SurModics Technology (as hereinafter defined) upon the terms and conditions set forth herein and SurModics desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

1. **DEFINITIONS**

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below:

- 1.1 “**Act**” shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and/or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., as such may be amended from time to time.
- 1.2 “**Affiliate**” shall mean with respect to any Party, (a) any other Person of which [*] or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, general partnership interest of such other Person are owned, controlled, or held, directly or indirectly by, or under common ownership or control with, such Party; or (b) any other Person that, directly or indirectly, owns, controls, or holds [*] (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of such Party or is otherwise able to control the direction of such Party.[*]

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- 1.3 **“Calendar Quarter”** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- 1.4 **“Calendar Year”** shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.5 **“cGMPs”** shall mean all applicable laws and regulations, including, without limitation, the laws and regulations applicable in the United States, European Union, and/or Japan, relating to the Manufacture (as defined in Article 8 and the Supply Agreement) of I-vation Platform, Products and/or Surgical Instruments.
- 1.6 **“Change of Control”** shall mean with respect to a Party: (a) the sale of all or substantially all of such Party’s assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least [*] of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a person or entity, or group of persons or entities, acting in concert to acquire more than [*] of the voting equity securities or management control of such Party.
- 1.7 **“Clinical Trial”** shall mean a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial, as applicable.
- 1.8 **“Combination Product”** shall mean the I-vation Platform incorporating a combination of two or more of the following: TA Compound(s), [*] or Licensed Other [*] Compound(s) as active ingredients and, for the purposes of Sections 5.2 through 5.6, in final form (a) for sale by prescription, over-the-counter or any other method, or (b) for administration in a Clinical Trial or post-Marketing Authorization clinical trial.
- 1.9 **“Commercially Reasonable Efforts”** shall mean (a) with respect to the efforts to be expended by a Party to accomplish a particular objective other than those covered by clause (b), the good faith and diligent efforts, consistent with the usual practice followed by such Party, to accomplish a similar objective under similar circumstances; and (c) [*] Commercially Reasonable Efforts shall be determined on a market-by-market basis for a particular Product, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the Product and the market(s) involved.
- 1.10 **“Competing Pharma Change of Control”** means a Change of Control involving a Person or group of Persons acting in concert (a) with collective worldwide sales of ethical pharmaceutical products in the Calendar Year that preceded the Change of Control were [*] or more, or (b) [*]

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- 1.11 **“Competing Product”** shall mean, with respect to a particular Product and country of sale, a product (a) using a [*]
- 1.12 **“Control,” “Controls” or “Controlled by”** shall mean with respect to any item of or right under SurModics Patent Rights, Merck Patent Rights, SurModics Know-How or Merck Know-How, or any other intellectual property rights, the possession of (whether by ownership or license, other than pursuant to this Agreement), or the ability of a Party or its Affiliates, as the case may be, to grant access to, or a license or sublicense of, such item or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to grant the other Party such access or license or sublicense.
- 1.13 **“Extraction Tool”** shall mean the surgical tool that is used to remove the Intravitreal Implant from the eye.
- 1.14 **“FDA”** means the U.S. Food and Drug Administration.
- 1.15 **“Field”** shall mean [*]
- 1.16 **“Filing”** of an NDA shall mean the acceptance by a Regulatory Authority of an NDA for filing.
- 1.17 **“First Commercial Sale”** shall mean, with respect to any Product, the first sale for end use or consumption of such Product in a country, excluding, however, any sale or other distribution for use in a Clinical Trial or post-Marketing Authorization clinical trial.
- 1.18 **“GLP” or “Good Laboratory Practice”** shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.
- 1.19 **“Improvements”** shall mean any and all enhancements, discoveries, inventions, additions, alterations, modifications, design changes and other improvements, whether or not patentable, with respect to the I-vation Platform and Surgical Instruments Controlled by SurModics or its Affiliates during the Term.
- 1.20 **“IND”** shall mean an Investigational New Drug application, Investigational Device Exemption, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.
- 1.21 **“Information”** shall mean any and all information and data including without limitation, all Merck Know-How, SurModics Know-How, and all other scientific, pre-clinical,

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clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.

- 1.22 **“Initiation,” “Initiates” or “Initiated”** shall mean, with respect to a Clinical Trial, the administration by Merck or its Affiliates of the first dose to a patient in such Clinical Trial.
- 1.23 **“Initiation of a Feasibility Study”** shall mean [*]
- 1.24 **“Initiation of IND-Enabling Study”** shall mean [*]
- 1.25 **“Insertion Tool”** shall mean the surgical tool that is used to insert the Intravitreal Implant into the eye.
- 1.26 **“Intravitreal Implant”** shall mean [*]
- 1.27 **“Invention”** shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived and/or reduced to practice as a result of the Research Program and/or a Feasibility Study conducted in accordance with this Agreement.
- 1.28 **“I-vation Platform”** shall mean [*]
- 1.29 **“I-vation TA Product”** shall mean the Intravitreal Implant incorporating a TA Compound as evaluated in the STRIDE Clinical Trial.
- 1.30 **“JHU License Agreement”** means that certain license agreement entered into on or about September 4, 2001 between The Johns Hopkins University (“JHU”) and InnoRx, Inc. (“InnoRx”) relating to Drug Delivery, the Addendum entered into on or about November 14, 2003, the Second Addendum entered into on or about December 21, 2004, the Amendment entered into January 14, 2005, the Third Addendum entered into on May 31, 2007, and the letter agreement dated as of June 19, 2007.
- 1.31 **“Joint Program Information and Inventions”** shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, resulting from the Research Program and/or the Feasibility Studies, whether or not patentable, developed or invented jointly by employee(s) of Merck, its Affiliates and/or a Third Party acting on behalf of Merck or its Affiliates within the scope of the Research Program and/or the Feasibility Studies, on the one hand, and employee(s) of SurModics, its Affiliates and/or a Third Party acting on behalf of SurModics or its Affiliates within the scope of the Research Program and/or the Feasibility Studies, on the other hand.
- 1.32 **“Joint Program Know-How”** shall mean all Joint Program Information and Inventions that are not claimed or covered by Joint Program Patent Rights.

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- 1.33** “**Joint Program Patent Rights**” shall mean any and all Patent Rights which during the Term are Controlled by SurModics and Merck (or their respective Affiliates) in accordance with Section 2.8.1(c) that claim or cover Joint Program Information and Inventions.
- 1.34** “**JRC**” or “**Joint Research Committee**” shall mean the joint research committee established to facilitate the Research Program and Feasibility Studies, as more fully defined in Section 2.5.1.
- 1.35** [*]
- 1.36** [*]
- 1.37** “**Know-How Royalty**” shall have the meaning given such term in Section 5.2.1(b).
- 1.38** “**Licensed Other [*] Compounds**” shall mean the Other [*]
- 1.39** “**Major EU Market**” shall mean [*]
- 1.40** “**Marketing Authorization**” shall mean all approvals and permits from the relevant Regulatory Authority necessary to market and sell a Product and/or Surgical Instrument in any country (including without limitation, all applicable pricing and governmental reimbursement approvals even if not legally required to sell Product or Surgical Instrument(s) in a country).
- 1.41** “**Merck Program Information and Inventions**” shall mean all protocols, formulas, data, Inventions, know-how and trade secrets, resulting from the Research Program and/or Feasibility Study, whether or not patentable, and is developed or invented solely by employees of Merck or its Affiliates or Third Parties acting on behalf of Merck or its Affiliates within the scope of the Research Program and/or the Feasibility Studies.
- 1.42** “**Merck Know-How**” shall mean any information and materials, including but not limited to discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including without limitation Merck Program Information and Inventions and Merck’s rights in Joint Program Information and Inventions), know-how and trade secrets, patentable or otherwise, which as of the Effective Date and/or during the Term, (a) are Controlled by Merck or its Affiliates, (b) are not generally known and (c) are necessary to SurModics in the performance of its obligations under the Research Program, the Feasibility Studies and/or the manufacture and supply by SurModics of Clinical Supplies and commercial supply of the Products to Merck and its Related Parties in accordance with Article 8.
- 1.43** “**Merck Patent Rights**” shall mean Patent Rights which during the Term are Controlled by Merck or its Affiliates that claim or cover Merck Know-How.

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1.44 “**NDA**” shall mean a New Drug Application, Biologics License Application, Worldwide Marketing Application, Marketing Authorization Application, Premarket Approval (PMA), Premarket Notification filing pursuant to Section 510(k) of the US Food, Drug and Cosmetics Act, or similar application or submission for Marketing Authorization of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.45 “**Net Sales**” shall mean the gross amount invoiced for Products sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced:

- (a) trade and quantity discounts other than early payment cash discounts;
- (b) returns, rebates, chargebacks and other allowances;
- (c) retroactive price reductions that are actually allowed or granted;
- (d) [*]
- (e) [*]

For the avoidance of doubt, the gross amount invoiced for Products will not include value added taxes and other similar taxes on Product.

1.46 “**Other [*] Compound(s)**” shall mean [*]

1.47 “**Other [*] Product(s)**” shall mean the [*] and, for the purposes of Sections 5.2 through 5.6, that is in final form (a) for sale by prescription, over-the-counter or any other method, or (b) for administration in a Clinical Trial or post-Marketing Authorization clinical trial.

1.48 “**Party**” shall mean Merck and SurModics, individually, and “**Parties**” shall mean Merck and SurModics, collectively.

1.49 “**Patent Rights**” shall mean any and all issued patents and patent applications in the Territory (which for the purposes of this Agreement shall be deemed to include certificates of invention and applications for certificates of invention) and any divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, supplementary protection certificates, pediatric exclusivity periods, any other patent term extensions and exclusivity periods and the like of any such patents and patent applications, and any and all U.S. and foreign equivalents of the foregoing.

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- 1.50 **“Person”** shall mean any individual, corporation, joint venture, limited liability company, partnership, limited partnership, limited liability partnership, trust or any other private, public or governmental entity.
- 1.51 **“Phase I Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).
- 1.52 **“Phase II Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).
- 1.53 **“Phase III Clinical Trial”** shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).
- 1.54 **“Polymers”** shall mean [*]
- 1.55 **“Product(s)”** shall mean TA Product(s), [*], Other [*] Product(s), or Combination Product(s), individually or collectively, unless otherwise specified and, for the purposes of Sections 5.2 through 5.6, that is in final form (a) for sale by prescription, over-the-counter or any other method, or (b) for administration in a Clinical Trial or post-Marketing Authorization clinical trial.
- 1.56 **“Program Patent Rights”** shall mean the Joint Program Patent Rights and SurModics Program Patent Rights.
- 1.57 **“Regulatory Authority”** shall mean any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of a Product or Surgical Instrument in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.
- 1.58 **“Regulatory Related Documents”** shall mean all documents and records filed with or relied upon on in any filings with Regulatory Authorities with respect to any chemistry, manufacturing or control information, non-clinical studies or Clinical Trial relating to the TA Product conducted by or on behalf of SurModics as of the Effective Date, including, without limitation, documents relating to the STRIDE Clinical Trial and the planned Phase II Clinical Trial for the TA Product. Regulatory Related Documents shall include without limitation the documents and records listed on Schedule 1.58 attached hereto.
- 1.59 **“Related Party”** shall mean each of Merck, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.
- 1.60 **“Research Program”** shall mean the research and development activities undertaken by the Parties hereto as set forth in Article 0. Unless otherwise specified, references herein to the Research Program shall include the separate research programs for each [*], as generally outlined on Schedule 2.1.

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- 1.61 **“Research Program Term”** shall with respect to [*], have the meaning given such term in Section 2.9. All references to Research Program Term shall be deemed to include any extension of the Research Program Term in accordance with such Section 2.9.
- 1.62 **“STRIDE Clinical Trial”** shall mean the Phase I Clinical Trial, commenced by SurModics prior to the Effective Date, assessing the safety and tolerability of the I-vation TA Product in patients with diabetic macular edema under the TA Product IND.
- 1.63 **“Supply Agreement”** shall mean the Supply Agreement, effective as of the Effective Date pursuant to which SurModics or its Affiliates (a) will Manufacture (as defined in the Supply Agreement) and supply Clinical Product or Marketed Product (as each such term is defined in the Supply Agreement) to Merck or its Related Parties, and (b) will provide scale up and transfer of manufacturing capabilities to Merck.
- 1.64 **“Surgical Instruments”** shall mean the Insertion Tool and/or the Extraction Tool, and any Improvements thereto.
- 1.65 **“SurModics Background Patent Rights”** shall mean [*]
- 1.66 **“SurModics Know-How”** shall mean [*]
- 1.67 **“SurModics Patent Rights”** shall mean the SurModics Background Patent Rights and [*]
- 1.68 **“SurModics Program Information and Inventions”** shall mean [*]
- 1.69 **“SurModics Program Know-How”** shall mean SurModics Joint Program Information and Inventions that are not claimed or covered by SurModics Program Patent Rights.
- 1.70 **“SurModics Program Patent Rights”** shall mean [*]
- 1.71 **“SurModics Program Technology”** shall mean SurModics Program Information and Inventions, including without limitation SurModics Program Patent Rights and SurModics Program Know-How.
- 1.72 **“SurModics Technology”** shall mean the [*]
- 1.73 **“TA Compound(s)”** shall mean [*].
- 1.74 **“TA Product”** shall mean the I-vation Platform incorporating a TA Compound as an active ingredient (which shall include without limitation the I-vation TA Product) and, for the purposes of Sections 5.2 through 5.6, that is in final form (i) for sale by prescription, over-the-counter or any other method, or (ii) for administration in a Clinical Trial or post-Marketing Authorization clinical trial.

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

1.75 “**TA Product IND**” shall mean the IND submitted by SurModics to the FDA for authorization to conduct the STRIDE Clinical Trial.

1.76 [*]

1.77 “**Territory**” shall mean all of the countries in the world, and their territories and possessions.

1.78 “**Third Party**” shall mean an entity other than Merck and its Related Parties, and SurModics and its Affiliates.

1.79 “**Valid Patent Claim**” shall mean [*]

1.80 Other Definitions:

AAA	11.6.1
Adverse Experience	11.17
Agreement	Preamble
Clinical Data Package	2.1.4
Clinical Supplies	8.4.1(a)
[*]	3.2.2(a)
Compulsory License	5.2.3
Effective Date	Preamble
Excluded [*]	3.2.2(b)
Estimated Costs	2.3.2
Excluded Claim	11.6.7
Feasibility Study	3.2.3(a)
Human Materials	2.12
Indemnified Party	10.3
Indemnifying Party	10.3
Infringement Notice	7.4
Initial Work Period	2.3.2
InnoRx	1.30
JHU	1.30
Know-How Royalty	5.2.1(b)
Merck	Preamble
Materials	2.10
Option [*]	3.2.2(c)

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Other [*] License Option	3.2.1
Other [*] Compound Option Period	3.2.1(a)
Patent Royalty	5.2.1(a)
Program Coordinator	2.4
Progress Reports	3.5.3
Providers	2.12
SurModics	Preamble
Selection Notice	3.2.2(a)
Sensitive Information	11.2.3(d)
Serious	11.7
Supporting Documents	9.3.2
[*] Selection Fee	3.2.3(b)
Term	9.1
Third Party Notice	3.2.4
Third Party Patent License	5.2.4
Work Plan	2.3.2

2. **RESEARCH PROGRAM; REGULATORY MATTERS**

2.1 **Purpose; Responsibilities**

- 2.1.1 Purpose of Research Program.** SurModics and Merck shall engage in the Research Program for the TA Products, [*], upon the terms and conditions set forth in this Agreement. Merck may request that SurModics undertake certain activities in the course of the Research Program as generally outlined in Schedule 2.1, which schedule may be amended from time to time by the JRC in accordance with this Article 2. The objectives of the Research Program are [*]
- 2.1.2 Merck Responsibilities.** Merck shall have responsibility for the development of Products in the Territory within the scope of the rights granted to it hereunder and upon the terms and conditions set forth in this Agreement, and subject to SurModics' performance of its research and development obligations as set forth in this Article 2 and other obligations set forth in this Agreement.
- 2.1.3 SurModics Responsibilities.** SurModics shall collaborate with Merck in the development of the TA Products, [*], and shall provide support as may be reasonably requested by Merck, in accordance with the provisions of Section 2.3.
- 2.1.4 Initial delivery of I-vation TA Clinical Data Package and Transfer of Certain Other Documents and Files to Merck.** To facilitate the transfer of development responsibilities to Merck:

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(a) within seven (7) calendar days of the Effective Date, SurModics shall provide Merck with a “**Clinical Data Package**” (as delineated below) which shall consist of

- i. [*]
- ii. [*]
- iii. [*]

If Merck in good faith believes that the Clinical Data Package is not complete Merck may ask the JRC to meet, and in good faith discuss such concerns.

(b) After delivery of the Clinical Data Package to Merck, SurModics and its Affiliates shall:

- (i) within thirty (30) days after the Effective Date, transfer and assign to Merck the TA Product IND in electronic format and provide Merck with all Regulatory-Related Documents related thereto;
- (ii) as requested by Merck during the Term, provide Merck and, upon Merck’s request, its Related Parties with access to any regulatory submissions filed with any Regulatory Authorities and the data and know-how contained therein, including without limitation, Drug Master Files and Device Master Files, of SurModics and its Affiliates that relate to the I-vation Platform, TA Product, and the Surgical Instruments;
- (iii) as requested by Merck during the Term, cause its suppliers of the I-vation Platform and the TA Product to provide Merck and its Affiliates with access to any regulatory submissions filed with any Regulatory Authorities and the data and know-how contained therein, including without limitation, Drug Master Files and Device Master Files, of such Third Parties that relate to the I-vation Platform, TA Product, and the Surgical Instruments; and
- (iv) take such other steps with respect to the TA Product IND, Regulatory-Related Documents and Research Program as Merck may reasonably request.

2.2 Conduct of Research

2.2.1 Conduct of Research Program. SurModics and Merck shall each proceed with its respective responsibilities under the Research Program in accordance with the

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terms of this Agreement. SurModics and Merck shall each conduct its respective responsibilities under the Research Program in good scientific manner, and in compliance in all material respects with all requirements of applicable laws, rules and regulations and all applicable Good Laboratory Practices and attempt to achieve their objectives efficiently and expeditiously. SurModics and Merck each shall proceed diligently with the work set out in the Research Program by using their respective Commercially Reasonable Efforts to allocate sufficient time, effort, equipment and facilities to the Research Program and to use personnel with sufficient skills and experience as are required to accomplish the Research Program in accordance with the terms of this Agreement and Schedule 2.1.

2.2.2 Use of Third Parties. Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Research Program activities. SurModics shall be entitled to utilize the services of Third Parties to perform its Research Program activities only upon Merck's prior written consent or as specifically set forth in Schedule 2.1. Notwithstanding any such consent, each Party shall remain at all times fully liable for its respective responsibilities under the Research Program.

2.3 Outline, Specification and Funding of SurModics' Research Program Activities

2.3.1 Outline of SurModics' Research Program Activities. SurModics' research and development activities under this Article 2 are outlined on Schedule 2.1, which generally fall within the scope of the following areas:

(a) [*]

(b) [*]

(c) [*]

(d) [*]

(e) [*]

(f) [*]

(g) provide any other support or assistance that may be requested by Merck in connection with the research and development of the Products.

2.3.2 Establishing SurModics' Specific Responsibilities under the Research Program. With respect to the separate Research Programs (as generally outlined on Schedule 2.1) for each of the TA Product, [*], as the case may be, SurModics shall perform its responsibilities within the scope of the areas generally specified in Section 2.3.1 (or as otherwise agreed among the Parties) as requested by Merck. Merck shall compensate SurModics for its work under each Research

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Program as set forth in Section 2.3.3. For each Research Program, the specific work to be performed by SurModics under such Research Program shall be established pursuant to the procedures set forth below.

- (a) Subject to Section 2.3.2(b), with respect to each Research Program outlined on Schedule 2.1, no later than sixty (60) days prior to the commencement of any Calendar Quarter during the applicable Research Program Term, Merck shall notify SurModics in writing as to the general scope of the work Merck would like SurModics to perform during such Calendar Quarter (and, if Merck desires, covering up to the next four Calendar Quarters) under such Research Program. Merck may alternatively communicate such requests to SurModics through the JRC meetings and or the Program Coordinators. Promptly after delivery of such notification by Merck, Merck and SurModics shall, in good faith mutually agree through the JRC or the Program Coordinators upon a written work plan (each a “**Work Plan**”) describing the specific research and development activities to be performed by SurModics under each such Research Program during such Calendar Quarter (or for up to the next four Calendar Quarters, as the case may be), which shall also include a budget of SurModics’ estimated costs (including hourly task estimates and anticipated costs) to perform the Work Plan to be proposed by SurModics, and approved by Merck (“**Estimated Costs**”) reasonably sufficient to fund (in accordance with the reimbursement principles specified in Section 2.3.3) those research and development activities to be carried out by SurModics as contemplated in such Work Plan. Each Work Plan and its Estimated Costs shall be agreed by the Parties prior to the commencement of the applicable Calendar Quarter.
- (b) Schedule 2.3.2 sets forth the preliminary Work Plans (including the Estimated Costs) for the Research Programs for TA Products [*] (the “**Initial Work Period**”). Promptly after the Effective Date, the JRC shall meet in good faith to discuss and approve the Work Plan and Estimated Costs for SurModics work during the Initial Work Period (including any necessary adjustments thereto). The JRC shall endeavor to approve the Work Plans and Estimated Costs for the Initial Work Period no later than thirty (30) days after the Effective Date. Following such JRC approval, SurModics shall perform the research and development activities (and Merck shall compensate SurModics) in accordance with such approved Work Plans and Section 2.3.

2.3.3 Merck’s Funding of SurModics Work Under a Work Plan.

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- (a) For research and development activities performed in accordance with each Work Plan, Merck will pay SurModics [*] basis [*] Merck will also reimburse SurModics for SurModics' [*]
 - (b) Periodically during each Research Program where SurModics is performing work under a Work Plan, and as requested by Merck, the Program Coordinators for each Party shall meet and discuss SurModics progress, [*] for work assigned to SurModics under any Work Plan. The goal of such discussions shall be to ensure that the contemplated work under a Work Plan is appropriately completed and performed within its Estimated Costs. SurModics shall also, on a monthly basis during each Calendar Quarter in which it is performing work under a Work Plan, provide Merck's Program Coordinator with an update of SurModics then current progress toward fulfilling its obligations under such Work Plan, together with a summary of its [*] for such work during such prior month.
 - (c) No later than [*] following the conclusion of each Calendar Quarter, in which SurModics has performed work under any Work Plan, SurModics shall provide Merck a detailed invoice for such Calendar Quarter setting forth a detailed list of the work actually performed by SurModics under the Work Plan(s) covering such Calendar Quarter, together with a detailed list of [*] Merck shall pay SurModics within [*] of Merck's receipt of a satisfactory invoice. Notwithstanding anything to the contrary in this Agreement, unless otherwise agreed to by the Parties, Merck's total financial obligations under any Work Plan shall not exceed the Estimated Costs for such Work Plan, and SurModics shall not be obligated to continue its performance under such Work Plan incurring costs and expenses in excess of the Estimated Costs.
 - (d) SurModics will keep (and cause its agents performing services under any Research Program to keep) true, accurate and complete records of [*] sufficient detail to permit determination of the costs of such goods and services, and will provide Merck's Program Coordinator with evidence of such costs to enable Merck's Program Coordinator to monitor and report on such expenses. [*]
- 2.3.4** SurModics shall require that all SurModics personnel, employees, consultants and agents involved in any of the Research Programs have entered into confidentiality and invention assignment agreements that are consistent with the provisions of this Agreement and shall be obligated to assign any rights they may have in any SurModics Program Technology and Joint Program Information and Inventions made during such work to SurModics consistent with any rights granted to Merck in any such Program Technology under this Agreement.

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2.4 **Program Coordinators**

Each Party shall appoint a representative to serve as the primary contact between the Parties with respect to the Research Program and to coordinate its respective activities under the Research Program (“**Program Coordinator**”). Each Party shall name its Program Coordinator and notify the other Party of such person promptly following the Effective Date. Each Party may change its Program Coordinator from time to time, in its sole discretion, effective upon providing written notice to the other Party of such change.

2.5 **Joint Research Committee**

The Parties hereby establish a committee to facilitate the Research Program and Feasibility Studies as follows:

- 2.5.1 Composition of the Joint Research Committee. The Research Program shall be conducted under the direction of a joint research committee (the “**JRC**”) comprised of [*] representatives of Merck and [*] representatives of SurModics. Each Party shall name its JRC representatives and notify the other Party of its JRC representatives promptly following the Effective Date. Each Party may change its representatives to the JRC from time to time, in its sole discretion, effective upon providing written notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Research Program. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JRC meetings, subject to such representative’s or consultant’s written agreement to comply with the requirements of Section 4.1. The JRC shall be chaired by a representative of Merck. Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.
- 2.5.2 Scope of JRC Oversight. The JRC’s oversight responsibilities shall be limited to the Research Program activities specified in Schedule 2.1 and the Feasibility Studies. Within such scope, the JRC shall:
- (a) [*]
 - (b) [*]
 - (c) [*]
 - (d) [*]
 - (e) [*]

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(f) [*]

(g) [*]

Notwithstanding anything to the contrary in the foregoing, the JRC shall not have any supervisory or decision making authority beyond the Research Program activities specified in Schedule 2.1 and Feasibility Studies.

2.5.3 Decision-Making. Decisions of the JRC shall be made unanimously, with each Party having one vote. [*]

2.5.4 Meetings. The JRC shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no less frequently than once per Calendar Quarter, with the location for such meetings alternating between SurModics and Merck facilities (or such other location as may be determined by the JRC). Alternatively, the JRC may meet by means of teleconference, videoconference or other similar communications equipment.

2.5.5 Termination of the JRC. All of the JRC's functions and duties with respect to each of the TA Products, [*] shall automatically terminate upon the conclusion of the Research Program Term related to such TA Products, [*], as the case may be; provided, however, thereafter during the Term Merck may, in its sole discretion, call a meeting of the JRC from time-to-time to discuss and exchange information regarding the Products and any other scientific and development information relating to the Products.

2.6 Exchange of Information

In addition to the obligations specified in Section 2.1.4, upon execution of this Agreement, and on an ongoing basis during the Research Program Term, SurModics shall promptly disclose to Merck in writing or in an electronic format all SurModics Know-How not previously disclosed and any SurModics Information and Inventions, including any Improvements relating to the I-vation Platform and Surgical Instruments as reasonably requested by or that may be reasonably necessary or useful for Merck to carry out its rights and obligations under this Agreement.

2.7 Records and Reports

2.7.1 Records. SurModics shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Research Program by SurModics.

2.7.2 Copies and Inspection of Records. Not more than [*] Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all

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such records of SurModics referred to in Section 2.7.1. Merck shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employees and/or Third Parties involved in the activities contemplated hereunder to visit the offices and laboratories of SurModics and any of its Third Party contractors as permitted under Section 2.2 during normal business hours and upon reasonable notice, and to discuss the Research Program work and its results in detail with the technical personnel of SurModics. Upon request, SurModics shall provide copies of the records described in Section 2.7.1.

2.7.3 Quarterly Reports. Within [*] following the end of each Calendar Quarter during the Term, SurModics shall provide to Merck a written progress report which shall describe the work performed to date on the Research Program, evaluate the work performed in relation to the goals of the Research Program and provide such other information as may be required by the Research Program or reasonably requested by Merck relating to the progress of the goals or performance of the Research Program.

2.8 Research Information and Inventions

2.8.1 Ownership of Information and Inventions. Subject to the licenses granted between the Parties under this Agreement, the entire right, title and interest in:

- (a) SurModics Program Information and Inventions shall be [*]
- (b) Merck Program Information and Inventions shall be [*]
- (c) Joint Program Information and Inventions shall be [*]

Within [*] following the end of each Calendar Quarter during the applicable Research Program Term, (i) SurModics shall disclose to Merck in writing the development, making, conception or reduction to practice of SurModics Program Information and Inventions and Joint Program Information and Inventions made during such Calendar Quarter (or in any previous Calendar Quarter if it had not yet been so disclosed by SurModics) and (ii) Merck shall disclose to SurModics in writing the development, making, conception or reduction to practice of Joint Program Information and Inventions made during such Calendar Quarter (or in any previous Calendar Quarter if it had not yet been so disclosed by Merck).

2.8.2 Inventorship. Inventorship of Inventions, whether or not patentable, conceived and/or reduced to practice by the Parties in the course of exercising rights or performing obligations pursuant to this Agreement, all related intellectual property rights, and all other information developed in the course of the Parties'

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exercise of rights under or performance of this Agreement shall be determined in accordance with the rules of inventorship under United States patent laws.

2.9 Research Program Term; Termination of Research Program

- 2.9.1 Term.** Except as otherwise provided herein, the initial term of the Research Program shall [*] The Parties may extend any Research Program Term by mutual written agreement of the authorized representative of the Parties, and shall, in such case, amend Schedule 2.1, as applicable. In addition, Merck may extend each such Research Program Term by an additional [*] period, for a total of up to [*] renewals by providing SurModics written notice of each such [*] renewal no later than [*] prior to the then termination date for such Research Program Term, in each such case the Parties shall amend Schedule 2.1 as applicable. The initial term and any subsequent extension term(s) with respect to the TA Product, [*] are collectively for each such Product referred to as the “Research Program Term” for such Product.
- 2.9.2 Termination by Merck.** At anytime during the Research Program Term, Merck, in its sole discretion, shall have the right to terminate any or all of the Research Programs or any Work Plan, by giving [*] advance written notice to SurModics. Upon termination of any or all of the Research Programs (or a particular Work Plan), or at any other time that Merck may request, SurModics agrees to return all Merck Information, the Materials, and all documents generated by SurModics in connection with the Research Program so terminated by Merck. Termination of a Research Program or a Work Plan under this Section 2.9.2 shall not affect either Party’s rights or obligations under this Agreement except (a) with respect to SurModics’ obligation to perform, and Merck’s obligation to fund, SurModics’ assigned responsibilities with respect to such terminated Work Plan and/or Research Program, as the case may be, under this Article 2; and (b) the non-exclusive licenses granted by Merck to SurModics under Section 3.3.1 shall terminate, solely as it pertains to any terminated Research Programs. **[*]**
- 2.9.3 Effect of Termination.** In the event of termination of a Research Program or any particular Work Plan, the Parties agree as follows:
- (a) Merck shall be responsible for funding SurModics only for [*] incurred in performance of services under, and for any non-cancelable commitments, made up to the effective date of such termination for, such Research Program or Work Plan, as the case may be; provided, however, in no case will Merck be required to pay SurModics for any [*] in excess of the Estimated Costs for the applicable Work Plan(s).

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(b) [*]

2.10 **Materials**

In order to facilitate the Research Program, each Party shall provide the other Party with sufficient quantities of material as set forth in Schedule 2.1 and other materials as each such Party may provide from time to time under this Agreement (the “**Materials**”). Merck shall provide SurModics with sufficient quantities of the [*] solely for the purpose of enabling SurModics to perform its activities under the Research Program in accordance with the terms of this Agreement. Each Party shall use the Materials supplied by the other Party solely for the purposes of carrying out its respective activities under the Research Program in accordance with the terms of this Agreement and, consistent with the licenses granted to either party under this Agreement. Neither Party shall transfer, deliver or disclose any such Materials of the other Party, or any derivatives, analogs, modifications or components thereof, to any Third Party without the prior written approval of the providing Party, except that Merck may transfer Materials provided by SurModics without SurModics’ prior written consent to Merck’s Related Parties, agents and subcontractors for the purpose of carrying out the development and commercialization of Products. The Materials supplied by Merck are not to be used in humans, except as contemplated by this Agreement and permitted by applicable law and shall not be transferred, delivered or disclosed to any Third Party by SurModics without the prior written approval of Merck. Any unused Materials supplied by Merck and any derivatives, analogs, modifications or components thereof to SurModics shall be, at Merck’s option, either returned to Merck, or destroyed in accordance with instructions by Merck.

2.11 [*]

[*]

2.12 **Use of Human Materials**

If any human primary cell lines, human tissue, human clinical isolates or similar human-derived materials (“**Human Materials**”) have been or are to be collected and/or used in the Research Program and Feasibility Studies, each Party represents and warrants (i) that it has complied, or shall comply, with all applicable laws, guidelines and regulations relating to the collection and/or use of the Human Materials and (ii) that it has obtained, or shall obtain, all necessary approvals and appropriate informed consents, in writing, for the collection and/or use of such Human Materials. Each Party shall provide documentation of such approvals and consents upon Merck’s request. Each Party further represents and warrants that such Human Materials may be used as contemplated in this Agreement without any obligations to the individuals or entities (“**Providers**”) who contributed the Human Materials, including, without limitation, any obligations of

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compensation to such Providers or any other Third Party for the intellectual property associated with the Human Materials or the commercial use thereof for any purposes.

3. LICENSES; DEVELOPMENT AND COMMERCIALIZATION

3.1 License Grants to Merck

3.1.1 Exclusive License Grants. SurModics hereby grants to Merck the following licenses:

- (a) an exclusive license (even as to SurModics) in the Territory under the SurModics Patent Rights, and Program Patent Rights to research, develop, make, have made, use, offer to sell, sell, have sold, import and export the Products in the Field;
- (b) an exclusive license (even as to SurModics) in the Territory under the SurModics Know-How, the SurModics Program Know-How, and SurModics' rights in Joint Program Know-How to research, develop, make, have made, use, offer to sell, sell, have sold, import and export the Products in the Field; and
- (c) an exclusive license (even as to SurModics) in the Territory under the SurModics Technology to research, develop, make, have made, use, offer to sell, sell, have sold, import and export the Surgical Instruments solely for use with, or in connection with the sale of, the Products in the Field.

Notwithstanding the license grants set forth above, SurModics shall retain those rights under the SurModics Technology that are necessary to perform SurModics' obligations under the Research Program and the Feasibility Studies in accordance with Article 2 and to manufacture and supply clinical supplies and commercial supply of Product to Merck and its Related Parties and the scale up and transfer of manufacturing capabilities to Merck in accordance with Article 8 and the Supply Agreement.

3.1.2 Non-Exclusive License Grant. Subject to the terms and conditions of this Agreement, SurModics hereby grants to Merck a non-exclusive, royalty-free license in the Territory under the SurModics Program Technology, for any and all uses, including without limitation, to research, develop, make, have made, use, offer to sell, sell, have sold, import and export a product other than the Products.

3.1.3 [*]

3.1.4 [*]

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

3.2 **Option for Exclusive Other [*] Licenses**

3.2.1 **Option to Acquire Other [*] Licenses.** Subject to Third Party rights granted by SurModics as of the Effective Date, or otherwise granted by SurModics after the Effective Date as set forth under Section 3.2.4 (in each case, so long as such Third Party Rights remain in effect) and the terms and conditions of this Section 3.2.1, SurModics hereby grants to Merck an option to enter into [*] additional [*] licenses in the Territory under the SurModics Technology to research, develop, make, have made, use, offer to sell, sell, have sold, import and export the I-vation Platform incorporating Other [*] Products in the Field (each an “**Other [*] License Option**”).

(a) **Other [*] Option Period.** The Other [*] License Option may be exercised by Merck at any time within [*] following the Effective Date [*] (the “**Other [*] Option Period**”). Notwithstanding the previous sentence, in the event that a Feasibility Study for a [*] in accordance with Section 3.2.2 is not completed before the expiration of the Other [*] Option Period, Merck’s Other [*] License Option with respect to those Other [*] Compounds that include the [*] shall be extended and remain exercisable by Merck until [*] after Merck’s receipt of the results of such Feasibility Study in accordance with Section 3.2.3(b).

(b) [*]

3.2.2 **Selection Notice.**

(a) During the Other [*] Option Period, Merck may identify in writing to SurModics (each a “**Selection Notice**”) [*]

(b) Within [*] days of receipt of a Selection Notice, [*] In the event that SurModics determines that either condition set forth in the previous sentence is true, then the [*] identified in the Selection Notice shall be considered an “**Excluded [*]**.”

(c) If SurModics determines that a [*] described in a Selection Notice is an Excluded [*], then SurModics will notify Merck in writing of the grounds for the exclusion during the forty-five [*] period described above.

(d) [*]

(e) [*]

(f) For the purposes of clarity, SurModics’ obligations under this Section 3.2.2 shall no longer apply following expiration of the Other [*] Compound Option Period, [*]

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3.2.3 Feasibility Study.

- (a) [*] Merck and SurModics shall in good faith mutually design and agree on a work plan to evaluate the use of the I-vation Platform [*] (each a “**Feasibility Study**”) and enter into a Feasibility Study Agreement therefore in the form attached hereto as Schedule 3.2.3. Both Merck and SurModics shall use their Commercially Reasonable Efforts to conduct the Feasibility Study at Merck’s cost and in accordance with the work plan set forth in the Feasibility Study Agreement in as expeditious manner as practicable.
- (b) At any time [*] but no later than [*] days after Merck’s receipt of the results of such Feasibility Study, Merck may exercise the [*] Option with respect to such [*] upon payment to SurModics of [*] (the “[*] **Selection Fee**”).

3.2.4 SurModics’ Obligations. Subject to the terms and conditions of this Agreement, including Sections 2.11, 3.1 and 3.2.4, SurModics shall be free to grant rights under the SurModics Technology to any Third Party without restriction or obligation to Merck. [*]

3.2.5 Other [*] Exclusive License Grant. Subject to the terms and conditions of this Section 3.2 and upon Merck’s exercise of the Other [*] Option with respect to Other [*] Compounds incorporating a particular [*] as set forth in Section 3.2.3(b), such Other [*] Compounds shall be included within the definition of Licensed Other [*] Compounds, and Merck shall automatically be granted an exclusive license under the SurModics Technology under, and in accordance with, the license grants provided in Section 3.1 and subject to payment of the [*] Selection Fee therefor in accordance with Section 3.2.3(b).

3.2.6 [*]

3.3 License Grants to SurModics

3.3.1 Non-Exclusive License Grant. Merck hereby grants to SurModics a non-exclusive, non-sublicensable (except to the extent SurModics is permitted to use a Third Party in performing its obligation under the Research Program in accordance with Section 2.2.2), royalty-free license in the Territory under Merck Program Information and Inventions, Merck Know-How and Merck Patent Rights for the sole purpose of discharging SurModics’ obligations under the Research Program during the Research Program Term, the Feasibility Studies during the term of each such Feasibility Study and the manufacture and supply by SurModics of clinical supplies and commercial supply of Product to Merck and its Related Parties and the scale up and transfer of manufacturing capabilities to Merck in accordance with Article 8 and the Supply Agreement.

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3.4 No Implied Licenses; Reservation of Rights

Except as specifically set forth in this Agreement, neither Party, its Affiliates or Related Parties shall acquire any license or other rights of any kind, whether by implication, estoppel or otherwise, in any Information disclosed to it under this Agreement or under any patents, patent applications or other intellectual property rights owned or Controlled by the other Party or its Affiliates.

Merck acknowledges that SurModics' business involves the application of the SurModics Technology to numerous drugs and other products and that SurModics retains the right (expressly subject to SurModics' obligations under this Agreement or under any other agreement between the Parties) to apply such SurModics Technology to drugs or products owned by SurModics or any Third Party and to make, use or sell drugs or products owned by SurModics or any Third Party. For the avoidance of doubt, no license is conferred to Merck under the SurModics Technology (other than the non-exclusive right set forth in Section 3.1.2) to research, develop, make, have made, use, offer to sell, sell, have sold, import, export or otherwise deal in or with any product, item, device or technology other than Products in the Field, and SurModics retains and reserves all rights that are not explicitly granted to Merck herein, including the sole and exclusive right to use and exploit SurModics Technology to research, develop, make, have made, use, offer to sell, sell, have sold, import, export or otherwise deal in any product, process, item, device, machine or other apparatus that is not a Product, including any I-vation Platform incorporating any compound(s) other than TA Compounds, [*].

3.5 Development and Commercialization

3.5.1 Merck shall use Commercially Reasonable Efforts to develop and commercialize a TA Product, a [*] and, if applicable, an Other [*] Product for each Licensed Other [*] Compound, as the case may be, on a commercially reasonable basis in such countries in the Territory where it is commercially viable to do so. Merck's diligence obligations under this Section 3.5 shall be subject to Section 3.6 and SurModics performing its obligations under the applicable Research Program in accordance with Article 2 and SurModics' rights and obligations to manufacture and supply the clinical supply of Product and/or the commercial supply of Products and/or the scale up and transfer of manufacturing capabilities to Merck in accordance with Article 8 and the Supply Agreement.

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3.5.2 [*]

3.5.3 [*]

3.5.4 [*]

3.5.5 [*]

3.6 Excused Performance

In addition to the provisions of Article 6, the obligations of Merck with respect to any Product under Article 2 and Section 3.5 are expressly conditioned upon the continuing absence of any material adverse condition or event relating to the safety or efficacy of the Product, and the obligation of Merck to develop or market any such Product shall be delayed or suspended so long as in Merck's opinion any such condition or event exists.

4. CONFIDENTIALITY AND PUBLICATION

4.1 Nondisclosure Obligation

All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

- (a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
- (b) is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;
- (c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;
- (d) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;
- (e) is disclosed to governmental or other regulatory agencies in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations;

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- (f) is deemed necessary by Merck to be disclosed to Related Parties, agents, consultants, and/or other Third Parties for any and all purposes Merck deems necessary or advisable in the ordinary course of business in accordance with this Agreement on the condition that such Third Parties agree to be bound by the confidentiality and non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for such Third Parties shall be no less than ten (10) years; or
- (g) is deemed necessary by counsel to the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party, on the condition that such attorneys, independent accountants and financial advisors agree to be bound by the confidentiality and non-use obligations contained in this Agreement; provided, however, that the term of confidentiality for such attorneys, independent accountants and financial advisors shall be no less than ten (10) years.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

If a Party is required by Federal, State or other applicable law by a court of competent jurisdiction, or other judicial or administrative process to disclose Information that is subject to the non-disclosure provisions of this Section 4.1 or Section 4.2, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 4.1 and Section 4.2, and the Party disclosing Information pursuant to law or court order shall take all steps reasonably necessary, including without limitation obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information.

4.2 SurModics Know-How

SurModics agrees to keep all SurModics Know-How solely related to the Products in the Field confidential subject to exceptions (b) or (e) in Section 4.1, and SurModics' reservation of rights as set forth in Section 3.4.

4.3 Publication

Merck and SurModics each acknowledge the other Party's interest in publishing the results of its research in order to obtain recognition within the scientific community and to advance the state of scientific knowledge. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Consequently, except for disclosures permitted pursuant to

Section 4.1, either Party, its employees or consultants wishing to make a publication shall deliver to the other Party a copy of the proposed written publication or an outline of an oral disclosure at least [*] prior to submission for publication or presentation. The reviewing Party shall have the right (a) to propose reasonable modifications to the publication or presentation for patent reasons, trade secret reasons or business reasons or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the reviewing Party requests a delay, the publishing Party shall delay submission or presentation for a period of [*] to enable patent applications protecting each Party's rights in such information to be filed in accordance with Article 7. Upon expiration of such [*] the publishing Party shall be free to proceed with the publication or presentation. If the reviewing Party requests modifications to the publication or presentation, the publishing Party shall edit such publication to prevent disclosure of trade secret or proprietary business information prior to submission of the publication or presentation. Notwithstanding anything to the contrary, publications or presentations made by either Party covered by the provisions of this Section 4.3 shall be limited to the results of research or other activities performed solely as part of the Research Program. Subject to any obligations of confidentiality it may have to Third Parties, SurModics will provide Merck with a courtesy copy of any publication or presentation by SurModics not otherwise covered by this Section 4.3 that relates to the I-vation Platform at least one (1) week prior to such publication.

4.4 Publicity/Use of Names

Upon execution of this Agreement, the Parties agree that the Parties shall issue a joint press release which shall be substantially in the applicable form attached hereto in Schedule 4.4. No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by law or government regulation.

Each Product shall be marketed under trademarks, including logos, slogans, trade dress, domain names, and other intellectual property, selected by Merck. Notwithstanding anything to the contrary in the foregoing, in the event Merck desires to use SurModics' I-vation™ trademark in connection with the marketing, promotion and/or sale of any Product, it shall so notify SurModics and SurModics shall grant Merck a non-exclusive, royalty-free, perpetual license to such trademark, with a right of sublicense, solely for the marketing, promotion and sale of Products in the Field in the Territory in accordance with this Agreement.

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4.5 Certain Obligations of SurModics

Notwithstanding anything in this Article 4 to the contrary, [*] to the extent necessary for SurModics to comply with its obligations and/or enforce its rights under the JHU License Agreement; provided that JHU shall be subject to appropriate written obligations of confidentiality and non-use with respect to such disclosures and JHU shall be obligated to only use such disclosed information for the purposes of the JHU License Agreement.

5. PAYMENTS; ROYALTIES AND REPORTS

5.1 License Fee and Milestone Payments

- 5.1.1** License Fee. In consideration for the licenses granted as set forth in Section 3.1 and the other rights granted under this Agreement, upon the terms and conditions contained herein, Merck shall pay to SurModics Twenty Million Dollars (USD \$20,000,000) within thirty (30) days after the Effective Date.
- 5.1.2** [*] Subject to the terms and conditions of this Agreement, Merck shall pay to SurModics [*] following the achievement of each such milestone, and shall make the appropriate milestone payment within [*] after the achievement of such milestone. For the sake of clarity, [*]
- 5.1.3** [*].

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

(a) Subject to the terms and conditions of this Agreement, with respect to [*] and the [*] of [*] respectively, Merck shall pay to SurModics the following milestone payments based upon the achievement of each of the corresponding clinical development milestones.

[*]

(b) Merck shall notify SurModics in writing within [*] following the achievement of each milestone event set forth in this Section 5.1.3, and shall make the appropriate milestone payment within [*] after the achievement of such milestone event. The milestone payments set forth in this Section 5.1 shall be payable only upon the initial achievement of the particular milestone event for each Product and no amounts shall be due hereunder for subsequent or repeated achievement of such milestone event for such Product. In the event that a [*] development milestone event is skipped for a particular Product, the milestone payment that would have otherwise been due for such skipped milestone event shall become due and payable upon the achievement of the next to occur [*] development milestone event for such Product.

(c) [*]

5.2 **Royalties**

5.2.1 Royalties Payable By Merck. Subject to the terms and conditions of this Agreement, Merck shall pay SurModics royalties, calculated on a Product-by-Product basis, as set forth in this Section 5.2.1.

(a) Patent Royalties. Subject to the other provisions of this Section 5.2, Merck shall pay SurModics royalties in an amount equal to a certain percentage of Net Sales of Products by Merck or its Related Parties as set forth below; provided that the sale of such Products would infringe a Valid Patent Claim in the country of sale but for the licenses granted to Merck by SurModics (“**Patent Royalty**”):

(i) [*]

(ii) [*]

(aa) [*];

(bb) [*].

(iii) [*]

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

(aa) [*];

(bb) [*].

(iv) [*]

(b) Know-How Royalty. Notwithstanding the provisions of Section 5.2.1(a), and subject to the other provisions of this Section 5.2, in countries where the sale of Product by Merck or its Related Parties would not infringe a Valid Patent Claim, Merck shall pay royalty rates that shall be set at [*] of the applicable royalty rate determined according to Section 5.2.1 (“**Know-How Royalty**”). The Parties agree and acknowledge that the payment of Know-How Royalties by Merck to SurModics for Net Sales in a country in which there is no Valid Patent Claim covering the applicable Product shall represent consideration for the license grant as set forth in Section 3.1.1(b).

(c) [*]

All royalties are subject to the following conditions:

- (i) that only one royalty shall be due with respect to the same unit of Product, including without limitation, subject to Section 5.2.1(iv), for any Combination Products;
- (ii) that no royalties shall be due upon the sale or other transfer among Merck or its Related Parties, but in such cases the royalty shall be due and calculated upon Merck’s or its Related Party’s Net Sales to the first independent Third Party;
- (iii) no royalties shall accrue on the sale or other disposition of Product by Merck or its Related Parties for use in a Clinical Trial, or other clinical trial, in the latter case conducted after the First Commercial Sale of Product; and
- (iv) no royalties shall accrue on the disposition of Product in reasonable quantities by Merck or its Related Parties as samples (promotion or otherwise) or as donations (for example, to non-profit institutions or government agencies for a non-commercial purpose).

5.2.2 [*]

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

5.2.3 [*]

5.2.4 [*]

5.2.5 [*]

5.2.6 [*]

5.3 **Reports; Payment of Royalty**

During the Term following the First Commercial Sale of a Product, Merck shall furnish to SurModics a quarterly written report for the Calendar Quarter showing the Net Sales on a country-by-country basis of all Products subject to royalty payments sold by Merck and its Related Parties in the Territory during the reporting period, total deductions and the royalties payable under this Agreement. Reports shall be due on the [*] day following the close of each Calendar Quarter. Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined.

5.4 **Audits**

- (a) Upon the written request of SurModics and not more than [*], Merck shall permit an independent certified public accounting firm of nationally and/or regionally recognized reputation selected by SurModics and reasonably acceptable to Merck, at SurModics' expense, to have access during normal business hours to such of the records of Merck as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any year ending not more than [*] prior to the date of such request. The accounting firm shall disclose to SurModics only whether the royalty reports are correct or incorrect and the amount of any discrepancy. No other information shall be provided to SurModics.
- (b) If such accounting firm correctly identifies a discrepancy made during such period, the appropriate Party shall pay the other Party the amount of the discrepancy as follows:
 - (i) if such audit uncovers an underpayment of royalties, Merck shall pay SurModics the amount of such underpayment within [*] of the date SurModics delivers to Merck such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. In such case, the fees charged by such accounting firm shall be paid by SurModics; provided, however, [*]
 - (ii) [*].

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- (c) Merck shall include in each sublicense granted by it pursuant to this Agreement a provision requiring the sublicensee to make reports to Merck, to keep and maintain complete and accurate records of sales made pursuant to such sublicense and to grant access to such records by SurModics' independent accountant to the same extent required of Merck under this Agreement. Upon the expiration of [*] following the end of any Calendar Year, the calculation of royalties payable with respect to such Calendar Year shall be binding and conclusive upon the Parties, and Merck and its Related Parties shall be released from any liability or accountability with respect to royalties for such Calendar Year and SurModics shall be released from any liability with respect to any overpayment by Merck for such Calendar Year.
- (d) SurModics shall treat all financial information subject to review under this Section 5.4 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with Merck and/or its Related Parties obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

5.5 Payment Exchange Rate

All payments to be made by Merck to SurModics under this Agreement shall be made in United States dollars and may be paid by check made to the order of SurModics or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by SurModics from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency equivalent in United States dollars due SurModics shall be made at the monthly rate of exchange utilized by Merck in its worldwide accounting system, prevailing on the third to the last business day of the month preceding the month in which such sales are recorded by Merck.

5.6 Income Tax Withholding

If applicable laws, rules or regulations require withholding of income or other taxes imposed upon any payments made by Merck to SurModics under this Article 5 of the Agreement, Merck shall make such withholding payments as may be required and shall subtract such withholding payments from such payments. Merck shall submit appropriate proof of payment of the withholding taxes to SurModics within a reasonable period of time. Merck shall promptly provide SurModics with the official receipts. Merck shall render SurModics reasonable assistance in order to allow SurModics to obtain the benefit of any present or future treaty against double taxation which may apply to such payments. If Merck did not withhold taxes, in whole or in part, in connection with any payment it made to SurModics under the Agreement and a tax authority subsequently disagrees with Merck's interpretation of the withholding rules and finds that

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Merck had a duty to withhold taxes and such taxes were assessed against and paid by Merck, then SurModics will indemnify and hold harmless Merck from and against such taxes, [*] If Merck makes a claim under this Section, it will comply with the obligations imposed by this Section as if Merck had withheld taxes from a payment to SurModics.

6. REPRESENTATIONS AND WARRANTIES

6.1 Mutual Representations and Warranties

Each Party represents and warrants the following as of the Effective Date of this Agreement:

- (a) **Corporate Power.** Such Party is duly organized and validly existing under the laws of the state of its organization and has full corporate power and authority to enter into this Agreement and carry out the provisions hereof.
- (b) **Due Authorization.** The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Party. This Agreement any other documents contemplated hereby constitute valid and legally binding obligations of such Party enforceable against it in accordance with their respective terms.
- (c) **Non-Contravention.** The execution, delivery and performance by such Party of this Agreement and any other agreements and instruments contemplated hereunder will not (i) in any material respect violate any statute, regulation, judgment order, decree or other restriction of any Governmental Authority to which such Party is subject, (ii) violate any provision of the corporate charter, by-laws or other organizational documents of such Party, or (iii) constitute a material violation or breach by such Party of any provision of any material contract, agreement or instrument to which such Party is a party or to which such Party may be subject although not a party.

6.2 SurModics Representations and Warranties

SurModics represents and warrants to Merck that as of the Effective Date of this Agreement:

- (a) Except as set forth on Schedule 6.2(a), SurModics and/or its Affiliates Control the SurModics Background Patent Rights and existing SurModics Know-How and, to the actual knowledge of SurModics (i) the SurModics Background Patent Rights and existing SurModics Know-How are free and clear of any liens, charges and encumbrances, and (ii) no other person, corporate or other private entity, or governmental entity or subdivision thereof has any claim of ownership whatsoever with respect to the SurModics Background Patent Rights or existing

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SurModics Know-How, including without limitation, any claims relating to inventorship with respect thereto.

- (b)** Schedule 1.65 sets forth and includes a true and correct copy of all SurModics Background Patent Rights which are necessary to the development, manufacture, use, sale and import of the I-vation Platform, TA Products [*] respect to [*]
- (c)** SurModics has not granted any right, license, or interest in, to, or under the SurModics Background Patent Rights or SurModics Know-How that is inconsistent with the rights, licenses, and interests granted to Merck under the terms and conditions of this Agreement. SurModics has the right to grant the licenses and rights herein granted to Merck.
- (d)** To SurModics' actual knowledge, the SurModics Know-How exists and SurModics has not received any written communications from any Third Party that any issued patent within the SurModics Background Patent Rights are invalid or unenforceable, in whole or in part.
- (e)** To SurModics' actual knowledge, SurModics has not received any written communications from any Third Party that the development, manufacture, use, sale or import of the I-vation Platform or TA Products would infringe the valid claims of any issued patent owned by any Third Party.
- (f)** [*]
- (g)** SurModics and its Affiliates have made available to Merck all information regarding SurModics Background Patent Rights and SurModics Know-How that, to the knowledge of SurModics, is reasonably likely to be material to the development and commercialization of Products in the Field in the Territory (as such development and commercialization is viewed by SurModics as of the Effective Date).
- (h)** [*]
- (i)** [*]
- (j)** [*]
- (k)** [*]
- (l)** [*]
- (m)** [*]

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(n) Neither SurModics nor any of its Affiliates is currently subject to an FDA consent decree or any other similar action of a Regulatory Authority.

6.3 SurModics Further Representations, Warranties and Covenants

SurModics represents and warrants to Merck that [*]

6.4 Merck Representations and Warranties

Merck represents and warrants to SurModics that as of the Effective Date of this Agreement:

- (a) Merck and/or its Affiliates Control the Merck Patent Rights and Merck Know-How existing as of the Effective Date and, to the actual knowledge of Merck (i) the existing Merck Patent Rights and Merck Know-How are free and clear of any liens, charges and encumbrances and (ii) no other person, corporate or other private entity, or governmental entity or subdivision thereof has any claim of ownership whatsoever with respect to the existing Merck Patent Rights or Merck Know-How.
- (b) Merck has not granted any right, license, or interest in, to, or under the Merck Patent Rights or Merck Know-How that is inconsistent with the rights, licenses, and interests granted to SurModics under the terms and conditions of this Agreement.
- (c) Merck has not received any written communications from any Third Party that any issued patent within Merck Patent Rights in existence as of the Effective Date is invalid or unenforceable, in whole or in part.
- (d) There are no known outstanding, unsatisfied claims, judgments or settlements against or owed by Merck relating to the Merck Patent Rights and Merck Know-How and, to the actual knowledge of Merck, there are no pending or threatened claims or litigation relating to the Merck Patent Rights and Merck Know-How.
- (e) To Merck's actual knowledge, Merck has not received any written communications from any Third Party that the development, manufacture, use, sale or import of any product incorporating its proprietary [*] would with respect to such [*] infringe the valid claims of any issued patent owned by any Third Party.

6.5 DISCLAIMER OF WARRANTIES

THE WARRANTIES EXPRESSLY PROVIDED IN THIS AGREEMENT ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES HEREUNDER, AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF

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MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES.

6.6 LIMITATION ON DAMAGES TO OTHER PARTY

IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY PUNITIVE, SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL OR EXEMPLARY DAMAGES OR SIMILAR DAMAGES OR LOSSES TO THE OTHER PARTY ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING BUT NOT LIMITED TO LOST PROFITS, REGARDLESS OF WHETHER ARISING FROM BREACH OF CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF THE PARTY IS ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE OR IF SUCH LOSS OR DAMAGE COULD HAVE BEEN REASONABLY FORESEEN; PROVIDED HOWEVER, THAT THE FOREGOING LIMITATION OF LIABILITY SHALL NOT APPLY TO THE LIABILITIES ARISING FROM EITHER PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT AND THIS SECTION 6.6 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 and 10.2 OR A PARTY'S RIGHT TO OBTAIN SUCH DAMAGES FOR A BREACH OF ARTICLE 4.

7. PATENT PROVISIONS

7.1 Filing, Prosecution and Maintenance of Patents

- (a) SurModics Patent Rights. SurModics agrees to file, prosecute and maintain in the Territory the SurModics Background Patent Rights licensed to Merck under this Agreement. Such patent filings, prosecution and maintenance shall be at SurModics' sole expense, discretion and control. SurModics agrees to file, prosecute and maintain in the Territory, as appropriate and upon appropriate consultation with Merck, patent applications directed to the SurModics Program Technology licensed to Merck under this Agreement.
- (b) Joint Program Information and Joint Program Inventions. With respect to Joint Program Information and Inventions, the Parties agree to select outside counsel acceptable to both Parties to file, prosecute and maintain in the Territory, upon appropriate consultation with the Parties, Joint Program Patent Rights. [*]
- (c) SurModics Program Technology. With respect to SurModics Program Technology, SurModics may elect not to file patent applications thereon and if so, SurModics shall notify Merck and Merck shall have the right to file such patent applications. In the event Merck elects to file, SurModics shall execute such

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documents and perform such acts at Merck's expense as may be reasonably necessary to effect an assignment of such SurModics Program to Merck in a timely manner to allow Merck to file such patent application.

- (d) SurModics Program Technology and Joint Program Information and Inventions. In each case involving patent applications filed covering SurModics Program Technology or Joint Program Information and Inventions, the filing Party shall give the non-filing Party an opportunity to review the text of the application before filing, shall consult with the non-filing Party with respect thereto, and shall supply the non-filing Party with a copy of the application as filed, together with notice of its filing date and serial number.
- (e) Notice to Merck. SurModics shall keep Merck advised of the status of the actual and prospective patent filings and, upon Merck's request, shall provide advance copies of any papers related to the filing, prosecution and maintenance of such patent filings. SurModics shall promptly give notice to Merck of the grant, lapse, revocation, surrender, invalidation or abandonment of any SurModics Patent Rights licensed to Merck for which SurModics is responsible for the filing, prosecution and maintenance.
- (f) Costs. Except as provided in this Section 7.1, with respect to all filings hereunder, the filing Party shall be responsible for payment of all costs and expenses related to such filings.

7.2 [*]

[*]

7.3 Interference, Opposition, Reexamination and Reissue

- (a) Each party shall, within [*] of learning of such event, inform other Party of any request for, or filing or declaration of, any interference, opposition, reissue or reexamination relating to SurModics Patent Rights or Program Patent Rights. Merck and SurModics shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Merck shall have the right to review and approve any submission to be made in connection with such proceeding pertaining to Program Patent Rights and Merck shall have the right to review and comment on any submission to be made in connection with SurModics Patent Rights.
- (b) SurModics shall not initiate any reexamination, interference or reissue proceeding relating to SurModics Patent Rights or Program Patent Rights without the prior written consent of Merck, which consent shall not be unreasonably withheld, or delayed.

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- (c) In connection with any interference, opposition, reissue, or reexamination proceeding relating to SurModics Patent Rights or Program Patent Rights, Merck and SurModics will cooperate fully and will provide each other with any information or assistance that either may reasonably request. SurModics shall keep Merck informed of developments in any such action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto.
- (d) The Parties shall share equally the expense of any interference, opposition, reexamination, or reissue proceeding relating to SurModics Patent Rights licensed to Merck under this Agreement, except to the extent that SurModics Patent Rights or Program Patent Rights have also been licensed to a Third Party then all parties shall share in the expense on a pro-rated basis.

7.4 **Enforcement and Defense**

- (a) During the Term, each of the Parties shall promptly notify the other in the event they learn of (i) any known or suspected infringement of SurModics Patent Rights or Program Patent Rights that cover a Product in the Field, or (ii) any known or suspected misappropriation or misuse of SurModics Know-How that covers a Product in the Field (the "**Infringement Notice**"). The Parties shall thereafter consult and cooperate fully to determine a course of action, including but not limited to the commencement of legal action by either or both Merck and SurModics, to terminate any infringement of the SurModics Patent Rights or Program Patent Rights or any misappropriation or misuse of the SurModics Know-How. However, SurModics, upon notice to Merck, shall have the first right to initiate and prosecute such legal action at its own expense and in the name of SurModics (or in the name of Merck and SurModics in the case of Joint Program Patent Rights), or to control the defense of any declaratory judgment action relating to SurModics Patent Rights, Program Patent Rights or SurModics Know-How. SurModics shall inform Merck if it elects not to exercise such first right promptly, but in no event later than [*] from the date of the Infringement Notice by either Party, and Merck shall thereafter have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of Merck and, if necessary, SurModics. Each Party shall have the right to be represented by counsel of its own choice.[*]
- (b) In the event that SurModics elects not to initiate and prosecute an action as provided in paragraph (a), and Merck elects to do so, the costs of any course of action to terminate such infringement of SurModics Patent Rights, Program Patent Rights or misappropriation or misuse of SurModics Know-How, including without limitation the costs of any legal action commenced or the defense of any declaratory judgment, shall be borne solely by Merck.

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- (c) For any action to terminate any infringement of SurModics Patent Rights or Program Patent Rights or any misappropriation or misuse of SurModics Know-How, in the event that Merck is unable to initiate or prosecute such action solely in its own name, [*] In connection with any action, Merck and SurModics will cooperate fully and will provide each other with any information or assistance that either may reasonably request. Each Party shall keep the other informed of developments in any action or proceeding, including, to the extent permissible by law, consultation on and approval of any settlement, the status of any settlement negotiations and the terms of any offer related thereto; provided, that neither Party may enter into a settlement or consent judgment or other voluntary final disposition of a suit under this Section that materially affects the other Party's rights or interests without the consent of the other Party, which consent shall not be unreasonably withheld, or delayed.
- (d) Any recovery (including without limitation royalties, settlement fees or other consideration) obtained by either or both Merck and SurModics in connection with or as a result of any action contemplated by this Section, whether by settlement or otherwise, shall be shared in order as follows:
 - (i) [*]
 - (ii) [*]
 - (iii) [*]
- (e) Notwithstanding anything herein to the contrary, the Parties' rights and obligations under this Section 7.4 shall apply only to the extent that any infringement, misappropriation or misuse pertains to SurModics Patent Rights, Program Patent Rights or SurModics Know-How that claim or cover one or more Products and this Section 7.4 shall not apply, and Merck shall have no rights hereunder, to the extent that any infringement, misappropriation or misuse pertains to SurModics Patent Rights, Program Patent Rights or SurModics Know-How that claim or cover any I-vention Platform incorporating a compound(s) other than TA Compounds, [*]

7.5 **Infringement**

- (a) If either Party or its Affiliates receives a written notice from a Third Party alleging that the development or commercialization of a Product infringes or otherwise violates the intellectual property rights of such Third Party, then such Party shall promptly notify the other Party in writing of the allegation. As soon as reasonably practicable after the receipt of such notice, the Parties shall meet and consider the appropriate course of action with respect to the allegation. The Parties shall at all times cooperate, share all material notices and filings in a

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timely manner, provide all reasonable assistance to each other. Each Party shall have the right to defend any action naming it. Neither Party may enter into a settlement or consent judgment or other voluntary final disposition of a suit under this Section that materially affects the other Party's rights or interests without the consent of the other Party, which consent shall not be unreasonably withheld, - or delayed. For the sake of clarity, the rights and obligations in this Section relating to notice, cooperation and limitations on settlement shall apply even if only one Party defends the relevant action.

- (b) SurModics shall inform Merck of any certification regarding any SurModics Patent Rights it has received pursuant to either 21 U.S.C. §§355(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) or its successor provisions, or any similar provisions in a country in the Territory other than the United States, and shall provide Merck with a copy of such certification within [*] of receipt. SurModics' and Merck's rights with respect to the initiation and prosecution of any legal action as a result of such certification or any recovery obtained as a result of such legal action shall be as defined in paragraphs 7.4(a)-(d); provided, however, that SurModics shall exercise its first right to initiate and prosecute any action and shall inform Merck of such decision within [*] of receipt of the certification, after which time Merck shall have the right to initiate and prosecute such action. Regardless of which Party has the right to initiate and prosecute such action, both Parties shall, as soon as practicable after receiving notice of such certification, convene and consult with each other regarding the appropriate course of conduct for such action. The non-initiating Party shall have the right to be kept fully informed and participate in decisions regarding the appropriate course of conduct for such action, and the right to join and participate in such action.

7.6 Cooperation; Patent Term Extension and Restoration

The Parties agree to cooperate and to take reasonable actions to maximize the protections available under the safe harbor provisions of 35 U.S.C. 103(c) for U.S. patents/patent applications. The Parties hereto shall cooperate with each other, including without limitation to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term extension, restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to SurModics Patent Rights. In the event that elections with respect to obtaining such patent term restoration are to be made, Merck shall have the right to make the election and SurModics agrees to abide by such election. All costs, fees and expenses incurred in obtaining patent term extensions, restorations or supplemental protection certificates shall be shared equally by SurModics and Merck.

7.7 [*]

[*]

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8. MANUFACTURING AND SUPPLY OBLIGATIONS

- 8.1** Pursuant to the terms of the Supply Agreement, SurModics agrees to Manufacture (as defined in the Supply Agreement), or have Manufactured, and supply Merck's and its Related Parties' requirements for (a) Clinical Product (as defined in the Supply Agreement) in the Territory for use in the Clinical Trials, the Research Program and other non-commercial uses by Merck, and its Related Parties, and (b) Marketed Product as defined in the Supply Agreement) for sale in the Territory.
- 8.2** SurModics shall provide the scale up and technology transfer services to Merck as specified in Sections 2.6 and 12.9(d) of the Supply Agreement. Such obligations shall survive termination of the Supply Agreement and constitute the obligations of SurModics under this Agreement as if fully set forth herein.

9. TERM AND TERMINATION

9.1 Term and Expiration

This Agreement shall be effective as of the Effective Date and unless terminated earlier pursuant to Sections 9.2 or 9.3, this Agreement shall continue in effect until expiration of all royalty obligations hereunder. Upon expiration of this Agreement, Merck's licenses pursuant to Section 3.1, if granted, shall become fully paid-up, perpetual licenses. For the purposes of this Agreement, "**Term**" shall mean the period commencing with the Effective Date through to the date of such expiration or earlier termination referenced in the first sentence of this Section, and in the event this Agreement is terminated or expires only with respect to TA Products, [*], "**Term**" of this Agreement as it applies to such Product shall terminate as of the effective termination or expiration date for such Product as specified in this Article 9.

9.2 Termination by Merck

Notwithstanding anything contained herein to the contrary, Merck shall have the right to terminate this Agreement, in its entirety or on a Product-by-Product basis, at any time in its sole discretion by giving [*] advance written notice to SurModics. No later than [*] after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information in tangible form received from the other Party and all copies thereof or in the case of termination with respect to a Product, Information with respect to such Product; provided, however, that each Party may retain any Information reasonably necessary for such Party's continued practice under any license(s) which do not terminate pursuant to this Section, and may keep one copy of Information received from the other Party in its confidential files for record purposes. In the event of termination under this Section 9.2: (i) each Party shall pay all amounts then due and owing as of the termination date; (ii) Merck's license pursuant to Section 3.1.2 shall become a perpetual license; and (iii) except for the surviving provisions set forth in this Section 9.2, Section 9.3.2(c) and Section 9.4, the rights and obligations of the Parties hereunder shall terminate as of the date of such termination or in the case of termination

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with respect to a Product, those rights and obligations of the Parties with respect to such Product shall terminate as of the date of such termination.

9.3 Termination for Cause

9.3.1 Cause for Termination. This Agreement may be terminated at any time during the Term:

- (a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder by causes and reasons within its control and has not cured such breach within [*] after notice requesting cure of the breach; provided, however, that in the event of a good faith dispute with respect to the existence of a material breach, the [*] as the case may be) cure period shall be tolled until such time as the dispute is resolved pursuant to Section 11.6;
- (b) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within [*] after the filing thereof.

9.3.2 Effect of Termination for Cause on License.

- (a) If SurModics terminates this Agreement under Section 9.3.1(a), (i) Merck's licenses pursuant to Section 3.1.1 and 3.1.4 shall terminate as of such termination date; (ii) Merck shall pay all amounts then due and owing as of the termination date; and (iii) Merck shall, within [*] after the effective date of such termination, return or cause to be returned to SurModics all Information in tangible form and all substances or devices delivered or provided by SurModics, as well as any other material provided by SurModics in any medium; provided that if SurModics terminates this Agreement pursuant to Section 9.3.1(a) for Merck's breach of its material obligation under Section 3.5, this Agreement shall be terminated only with respect to the particular Product for which such breach has occurred and the Agreement shall otherwise remain in full force and effect with respect to the remaining Products covered by this Agreement for which a breach of Section 3.5 has not occurred.
- (b) If Merck terminates this Agreement under Section 9.3.1(a), [*] In addition, (x) SurModics shall, within [*] after the effective date of such termination, return or cause to be returned to Merck all Information in

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tangible form, and all substances or compositions delivered or provided by Merck, including Merck Material, as well as any other material provided by Merck in any medium, and (y) SurModics obligations under Article 8 shall continue until satisfied.

- (c) Upon termination of this Agreement by Merck pursuant to Section 9.2, or by SurModics pursuant to Section 9.3.1(a), [*]
- (d) If this Agreement is terminated by Merck pursuant to Section 9.3.1(b) due to the rejection of this Agreement by or on behalf of SurModics under Section 365 of the United States Bankruptcy Code (the "Code"), all licenses and rights to licenses granted under or pursuant to this Agreement by SurModics to Merck are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against SurModics under the Code, Merck shall be entitled to a complete duplicate of, or complete access to (as Merck deems appropriate), any such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments thereof shall be promptly delivered to Merck (i) upon any such commencement of a bankruptcy proceeding upon written request therefor by Merck, unless SurModics elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under (i) above, upon the rejection of this Agreement by or on behalf of SurModics upon written request therefor by Merck.

The foregoing provisions of this Section 9.3.1(d) are without prejudice to any rights Merck may have arising under the Code or other applicable law.

9.4 Effect of Expiration or Termination; Survival

Expiration or termination, in its entirety or on a Product-by-Product basis, of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination, in its entirety or on a Product-by-Product basis, of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including without limitation the obligation to pay royalties for Products sold prior to such expiration or termination. In the case of termination of this Agreement with respect to a particular Product(s), only those provisions relating to such Products shall terminate and otherwise, the Agreement shall remain in full force and effect.

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

The provisions of Article 4 shall survive the expiration or termination of this Agreement and shall continue in effect for [*] In addition, the provisions of [*] shall survive any expiration or termination of this Agreement.

10. INDEMNIFICATION

10.1 Indemnification by Merck.

Merck agrees to indemnify, defend and hold harmless SurModics, its Affiliates and their respective directors, officers, employees and agents from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to or resulting from [*]

10.2 Indemnification by SurModics

SurModics agrees to indemnify, defend and hold harmless Merck, its Affiliates and their respective directors, officers, employees and agents from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to or resulting from [*]

10.3 Third Party Claim Procedure

A Person entitled to indemnification under this Article 10 (an “**Indemnified Party**”) shall give prompt written notification to the Person from whom indemnification is sought (the “**Indemnifying Party**”) of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party claim as provided in this Section 10.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [*] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified

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Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.

11. MISCELLANEOUS

11.1 Force Majeure

Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation, other than a payment obligation, under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including, but not limited to, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical, and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

11.2 Assignment/ Change of Control

11.2.1 Except as provided in this Section 11.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party.

11.2.2 Merck may, without SurModics' consent, assign this Agreement and its rights and obligations hereunder in whole or in part to a Merck Affiliate or in connection with a Change of Control and Merck may undergo a Change of Control.

11.2.3 SurModics may assign this Agreement in its entirety to the successor party in connection with a Change of Control and undergo a Change of Control; provided that SurModics shall provide written notice to Merck within at least [*] after the completion of such Change of Control, and if such Change of Control is a Competing Pharma Change of Control, Merck shall have the right, at Merck's

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election at any time after such Competing Pharma Change of Control has occurred, by written notice to SurModics to [*]

- (a) [*]
- (b) [*]
- (c) [*]
- (d) [*]

11.2.4 Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. Any attempted assignment not in accordance with this Section 11.2 shall be void.

11.3 Severability

If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

11.4 Notices

All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to SurModics, to: SurModics, Inc.
 9924 West 74th Street
 Eden Prairie, MN 55344

 Attn: Chief Executive Officer
 Facsimile: (952) 829-2743

with a copy to: SurModics, Inc.
 One Corporate Park, Suite 150
 Irvine, CA 92606

 Attn: President, Ophthalmology Division

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Fax: (949) 387-7465

If to Merck, to: Merck & Co., Inc.
One Merck Drive [*]
P.O. Box 100
Whitehouse Station, NJ 08889-0100

Attn: [*]
Facsimile: [*]

and: Merck & Co., Inc.
One Merck Drive [*]
P.O. Box 100
Whitehouse Station, NJ 08889-0100

Attn: [*]
Facsimile: [*]

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered, if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch, if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail.

11.5 Applicable Law

This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States, without reference to any rules of conflict of laws or renvoi.

11.6 Dispute Resolution

11.6.1 The Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof. If the Parties do not fully settle, and a Party wishes to pursue the matter, each such dispute, controversy or claim that is not an "Excluded Claim" shall be finally resolved by binding arbitration in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex

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Disputes of the American Arbitration Association (“AAA”), and judgment on the arbitration award may be entered in any court having jurisdiction thereof. [*]

- 11.6.2** The arbitration shall be conducted by a panel of three persons experienced in the pharmaceutical business: [*] after initiation of arbitration, each Party shall select one person to act as arbitrator; and the two Party-selected arbitrators shall select a third arbitrator [*] of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the AAA. The place of arbitration shall be New York, New York in the event that SurModics initiates a proceeding under this Section 11.6, and Minneapolis, Minnesota in the event that Merck initiates a proceeding under this Section 11.6. All proceedings and communications shall be in English.
- 11.6.3** Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party’s compensatory damages. Each Party shall bear its own costs and expenses and attorneys’ fees and an equal share of the arbitrators’ fees and any administrative fees of arbitration.
- 11.6.4** Except to the extent necessary to confirm an award or as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.
- 11.6.5** The Parties agree that, in the event of a dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.
- 11.6.6** With respect to any dispute brought by SurModics claiming that Merck has breached its diligence obligations under Section 3.5, no later than [*] after selection of the third arbitrator in accordance with Section 11.6.2, the Parties and their representatives shall hold a preliminary meeting with the arbitrators, to mutually agree upon and thereafter follow procedures seeking to assure that the arbitration will be concluded [*] from such meeting. Failing any such mutual

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agreement, the arbitrators will design and the Parties shall follow procedures to such effect.

11.6.7 As used in this Section, the term “**Excluded Claim**” shall mean a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark or copyright; or (b) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory.

11.7 Entire Agreement; Amendments

This Agreement contains the entire understanding of the Parties with respect to the Research Program and the licenses granted hereunder. Any other express or implied agreements and understandings, either oral or written, with regard to the Research Program or the licenses granted hereunder, including, without limitation, the Collaboration Agreement, dated June 22, 2005, are superseded by the terms of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representatives of both Parties hereto.

11.8 Affiliates

Each Party may perform its obligations hereunder personally or through one of more Affiliates, although each Party shall nonetheless be solely responsible for the performance of its Affiliates. Neither Party shall permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited thereunder from committing directly.

11.9 Headings

The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

11.10 Independent Contractors

It is expressly agreed that SurModics and Merck shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither SurModics nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

11.11 Waiver

The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any

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other right hereunder or of any other breach by or failure of such other Party, whether of a similar nature or otherwise.

11.12 Cumulative Remedies

No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

11.13 Waiver of Rule of Construction

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

11.14 Certain Conventions

Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, and (c) words using the singular shall include the plural, and vice versa.

11.15 Business Day Requirements

In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a business day then such notice or other action or omission shall be deemed to be required to be taken on the next occurring business day.

11.16 Counterparts

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

11.17 Adverse Experience Reporting

Subject to any duties of confidentiality owed to Third Parties, each Party agrees throughout the Term to notify the other Party within [*] in English of any information of which it becomes aware concerning any side effect, injury, toxicity or sensitivity

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reaction, and/or Feasibility Study incident, near incident, medical device report or any unexpected incident, and the severity thereof involving the I-vation Platform, the Surgical Instrument, TA Product, [*], whether or not determined to be attributable to the I-vation Platform or the Surgical Instruments (hereinafter “**Adverse Experience**”), where such Adverse Experience is serious and associated with the clinical uses, studies, investigations, tests or marketing of the I-vation Platform, the Surgical Instruments, TA Product, [*], whether or not determined to be attributable to the I-vation Platform or the Surgical Instruments. With respect to all other adverse experiences, each Party shall furnish the other Party with copies of such non-serious adverse experiences reported to such Party in connection with the clinical uses, studies, investigations, tests and marketing of the I-vation Platform, the Surgical Instruments, TA Product, [*], in English, within [*] after receipt. “**Serious**” as used in this Section refers to an experience which results in death, is immediately life threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization, or prolongation of existing hospitalization, or is a congenital anomaly, cancer or an overdose. Other important medical events that may jeopardize the patient or may require intervention to prevent one of the outcomes previously listed should also be considered serious. In addition, a device malfunction report (if the device failed to perform as intended and caused a serious event described in the criteria above) will be handled as a serious adverse experience report. All other medical device reports that suggest the device caused or contributed to a non-serious adverse experience should be handled as a non-serious experience report. Furthermore, each Party agrees throughout the term of the Agreement to notify the other Party in English of any Serious Adverse Experience which occurs in the Territory within [*] after such Party becomes aware of such event and of any Non-serious Adverse Experience which occurs in the Territory [*] after such Party becomes aware of such event.

It is understood and agreed that these adverse experience reporting requirement provisions are based on the policies and procedures of Merck and regulatory reporting requirements. Accordingly, in the event of changes to regulatory requirements for adverse experience reporting, SurModics agrees to comply with such revised notification requirements.

As soon as practicable after the Effective Date, but no later than the start of Merck Clinical Trials, the Parties shall enter into a separate and more detailed agreement concerning adverse experience exchange and reporting.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERCK & CO., INC.

SURMODICS, INC.

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

By: _____
Name:
Title:

By: _____
Name: Bruce J Barclay
Title: Chief Executive Officer

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

SURMODICS BACKGROUND PATENTS

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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SUMMARY

This schedule is provided to identify the scope of work and estimated budgets for 2007. This assumes that work will begin on [*] (and may be adjusted as appropriate based upon an actual later start date) and include continuation of the [*] [*] and initiation of [*] development work. This work is described broadly in the following sections of Schedule 2.1 Merck-SurModics Collaborative Research Program.

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The estimated budget for work conducted from [*] is approximately [*] The actual charges will be based upon [*]

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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FORM OF FEASIBILITY STUDY AGREEMENT

This Feasibility Study Agreement (this “**Study Agreement**”), dated as of _____, 200X is made by and between Merck & Co., Inc., a New Jersey corporation (“**Merck**”) and SurModics, Inc., a Minnesota corporation (“**SurModics**”) and confirms the terms under which Merck and SurModics will conduct a Feasibility Study pursuant to the Exclusive License and Research Collaboration Agreement between the Parties dated as of **[insert effective date]** (the “**License Agreement**”).

1. DEFINITIONS

All capitalized terms in this Study Agreement (whether used in the singular or the plural), unless otherwise defined herein shall have the meanings set for the License Agreement. In addition, the following terms as used in this Study Agreement, whether used in the singular or the plural shall have the meanings set forth in this **Section 1**. References to “Sections” in this Study Agreement shall be to Sections of this Study Agreement unless otherwise specifically provided.

1.1 “License Agreement” shall have the meaning given such term in the preamble to this Study Agreement

1.2 “Work Plan” shall mean the research to be conducted under this Study Agreement as described in **Attachment A**. The Work Plan format shall follow the format set forth in **Attachment C** attached hereto.

2. PURPOSE; WORK PLAN; THIRD PARTIES

2.1 The Parties have entered in to this Study Agreement pursuant to **Section 3.2.3** of the License Agreement to determine [*].

2.2 Each Party agrees to use Commercially Reasonable Efforts to perform its respective tasks under this Study Agreement and as set forth in the Work Plan. All work performed hereunder will be conducted under the direction of the JRC which shall have sole decision-making authority with respect to any amendments to the Work Plan in accordance with **Article 2** of the License Agreement.

2.3 Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Work Plan responsibilities. SurModics shall be entitled to utilize the service of Third Parties to perform its Work Plan activities only upon Merck’s prior written consent, or as

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specifically set forth in the Work Plan. Each Party shall ensure: (a) that all employees and permitted Third Parties involved in the Work Plan are subject to confidentiality provisions at least as stringent as those of this Study Agreement; (b) that each employee and permitted Third Party who works on the Work Plan is qualified by appropriate experience and qualifications to perform the Work Plan work assigned to such employee or permitted Third Party in a capable and professional manner; and (c) that each employee and permitted Third Party who works on the Work Plan has assigned their rights to inventions in a manner consistent with the provisions of **Section 7** of this Agreement.

3. [*]

Merck shall supply, [*] to carry out the Work Plan in accordance with this Study Agreement. [*]

4. **FUNDING OF FEASIBILITY STUDY**

The budget for the research and development activities performed in accordance with the Work Plan (“**Study Budget**”) is attached hereto as **Attachment B**. [*]

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5. **CONFIDENTIALITY**

All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

- (a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;
- (b) is in the public domain by use and/or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;
- (c) is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party;
- (d) is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records;
- (e) is required to be disclosed by Federal or State law, by a court of competent jurisdiction, or is disclosed to a governmental or other regulatory agency in order to obtain patents or to gain or maintain approval to conduct clinical trials or to market Product, but such disclosure may be only to the extent reasonably necessary to obtain patents or authorizations or as so required by law or a court of competent jurisdiction;
- (f) is deemed necessary by Merck to be disclosed to Related Parties, agents, consultants, and/or other Third Parties for any and all purposes Merck and its Affiliates deem necessary or advisable in the ordinary course of business in accordance with this Study Agreement on the condition that such Third Parties agree to be bound by the confidentiality and non-use obligations contained in this Study Agreement; provided, however, that the term of confidentiality for such Third Parties shall be no less than ten (10) years.

These obligations of confidentiality and non-use shall continue during the term of this Study Agreement and continue until the longer of (i) ten (10) years after termination or expiration of this Study Agreement or (ii) ten (10) years after termination or expiration of the License Agreement.

6. **REPORTS**

SurModics shall maintain records, in sufficient detail and in good scientific manner appropriate for patent purposes which shall fully and properly reflect all work done and all results achieved in performance of the Work Plan. Upon completion of the Feasibility Study, SurModics shall provide a complete written report of the Feasibility Study results to Merck (hereinafter the “**Feasibility Report**”) within fifteen (15) days after completion of the Feasibility Study. In addition to any other relevant results and information, the Feasibility Report shall contain such information as specified in the Work Plan.

Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all documents generated by SurModics relating to the Feasibility Study. Merck shall maintain such records and the information disclosed therein in confidence in accordance with **Section 5**. Merck shall have the right to arrange for its employees and/or consultants involved in the activities contemplated hereunder to visit the offices and laboratories of SurModics and any of its Third Party contractors as permitted under **Section 2.3** during normal business hours and upon reasonable notice, and to discuss the Feasibility Study work and its results in detail with the technical personnel of SurModics. Upon request, SurModics shall provide Merck with copies of all records related to the Feasibility Study.

7. **INVENTIONS**

7.1 Ownership of Information and Inventions. The entire right, title and interest in:

- (a) SurModics Program Technology [*]
- (b) Merck Program Information and Inventions [*]; and
- (c) Joint Program Information and Inventions shall be owned [*]. Subject to the licenses granted under Article 3 of the License Agreement and the exclusive efforts obligations set forth in Section 2.11 thereof, [*], without obligation to account to the other for exploitation thereof, or to seek consent of the other Party for the grant of any license thereunder.

Within thirty (30) days following the end of each Calendar Quarter during the term of this Agreement, (i) SurModics shall disclose to Merck in writing all SurModics Program Technology and Joint Program Information and Inventions developed or invented by employees of SurModics or its Affiliates or Third Parties acting on behalf of SurModics or its Affiliates during such Calendar Quarter, and (ii) Merck shall promptly disclose to SurModics in writing all Joint Program Information and Inventions and Merck Information and Inventions

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developed or invented by employees of Merck or its Affiliates or Third Parties acting on behalf of Merck or its Affiliates during such Calendar Quarter.

7.2 **Inventorship.** Inventorship of inventions, whether or not patentable, conceived and/or reduced to practice by the Parties in the course of exercising rights or performing obligations pursuant to this Study Agreement, all related intellectual property rights, and all other information developed in the course of the Parties' exercise of rights under or performance of this Agreement shall be determined in accordance with the rules of inventorship under United States patent laws.

8. **PUBLICATION**

Any publication of the Feasibility Study results by either Party shall be in accordance with **Section 4.3** of the License Agreement.

9. **COMPLIANCE WITH LAW**

Each Party shall conduct its respective tasks under the Work Plan in accordance with all applicable laws, rules and regulations. In addition, if animals are used as part of the Work Plan, SurModics will comply with the Animal Welfare Act or any other applicable local, state, national and international laws or regulations relating to the care and use of laboratory animals. Merck encourages SurModics to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care and treatment of such research animals. Any animals which receive the [*] in the course of the investigation, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes. SurModics will notify Merck in writing of any deviations from applicable regulatory or legal requirements. SurModics hereby certifies that it will not and has not employed or otherwise used in any capacity the services of any person debarred under Section 21 USC 335a in performing any Feasibility Study hereunder.

10. **LIABILITY**

Merck assumes no responsibility and shall have no liability for the nature, conduct or results of any research, testing or other work performed hereunder. THE [*] IS SUPPLIED "AS IS" AND IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. SURMODICS ACKNOWLEDGES

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THAT THE [*] IS EXPERIMENTAL IN NATURE AND MAY HAVE UNKNOWN HAZARDOUS CHARACTERISTICS, IT IS AWARE OF THE RISKS OF WORKING WITH EXPERIMENTAL MATERIALS AND THAT IT WILL STRICTLY ADHERE TO PROPER LABORATORY PROCEDURES FOR HANDLING CHEMICALS WITH UNKNOWN HAZARDS.

11. TERM AND TERMINATION

- 11.1 Term.** This Agreement shall continue in effect for a period of [*] from the date first written above unless earlier terminated pursuant to this **Section 11**.
- 11.2 Termination for Convenience.** Merck may terminate this Study Agreement upon thirty (30) days' written notice to SurModics.
- 11.3 Termination for Breach.** Either party shall have the right to terminate this Study Agreement upon thirty (30) days written notice to the other, in the event that the other party shall commit any serious or persistent breach of any material provision of this Study Agreement; provided, however, that if the Party receiving such notice of termination shall cure such breach within said (30) day period, or take steps to begin such cure if the cure cannot be fully effectuated in the thirty (30) day period, the Study Agreement shall continue in full force and effect.
- 11.4 Termination Triggered by Termination of License Agreement.** Termination of the License Agreement shall constitute and have the effect of termination of this Study Agreement.
- 11.5 Effect of Termination.** In the event of termination of this Study Agreement pursuant to **Section 11.2** above, Merck shall reimburse SurModics for the pro-rata costs incurred in performance of the Work Plan and for any non-cancelable commitments made up to the date of termination; provided, however, that in no case will reimbursement under this Study Agreement exceed the amount specified in the Study Budget. If this Study Agreement is terminated pursuant to **Section 11.3** above, then in addition to any other remedies available to Merck under the License Agreement, no such reimbursement will be paid by Merck to SurModics. Upon termination of this Study Agreement, or at any other time that Merck may request, SurModics agrees to return all Candidate Compound and all documents generated by SurModics in connection with the Feasibility Study to Merck.

12. SURVIVAL

The provisions of [*] and all definitions relating to the foregoing, shall survive termination or expiration of this Study Agreement.

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13. **NOTICES**

Any notices required or provided by the terms of this Study Agreement shall be in writing, addressed in accordance with this Section, and shall be delivered personally or sent by certified or registered mail, return receipt requested, postage prepaid or by nationally-recognized express courier services providing evidence of delivery. The effective date of any notice shall be the date of first receipt by the receiving Party. Notices shall be sent to the addressee given below or to such other addressee as the Party to whom notice is to be given may have provided to the other Party in writing in accordance with this provision.

If to Merck:

Attn: [*]
Merck & Co., Inc.
[*]
[*]
[*]

With a copy to:

[*]
Merck & Co., Inc.
P.O. Box 100
One Merck Drive
Whitehouse Station, NJ 08889-0100

If to SurModics:

Chief Executive Officer
SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344
Fax: 952-829-2743

With a copy to:

SurModics, Inc.
One Corporate Park
Suite 150
Irvine, CA 92606
Attn: Paul A. Lopez
Fax: 949-387-7465

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

14. REPRESENTATIONS, WARRANTIES AND INDEMNIFICATION PROVISIONS OF LICENSE AGREEMENT

The representations and warranties relating to SurModics Program Technology contained in the License Agreement are true and correct as of the date of this Study Agreement and shall apply hereto.

15. INCORPORATION OF THE LICENSE AGREEMENT

The Parties expressly acknowledge and agree that the provisions of the License Agreement are incorporated by reference herein, or by their terms otherwise apply hereto, and further agree that such provisions shall be given full effect in interpreting and enforcing this Study Agreement. In the event of any inconsistency between this Study Agreement and the License Agreement, the License Agreement shall control.

16. COUNTERPARTS

This Study Agreement may be executed (by facsimile or otherwise) in one or more counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute one and the same agreement.

IN WITNESS WHEREOF, the Parties have executed this Study Agreement as of the date first set forth above.

MERCK & CO., INC.

SURMODICS, INC.

By:
Name:
Title:

By:
Name:
Title:

[*]

[*]

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

FORM OF PRESS RELEASE

See Attached.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

THIRD PARTIES WITH PATENT PROSECUTION RIGHTS

[*]

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

SUPPLY AGREEMENT

by and between
SURMODICS, INC.
and
MERCK & CO., INC.

Supply Agreement

This Supply Agreement (this "Agreement"), is effective as of the 26th day of June, 2007 (the "Effective Date"), by and between SurModics, Inc., a company organized and existing under the laws of the state of Minnesota and having its principal office at 9924 West 74th Street, Eden Prairie, Minnesota 55344 (hereinafter referred to as "SURMODICS"), and Merck & Co., Inc., a company organized and existing under the laws of the state of New Jersey U.S.A. and having its principal office at One Merck Drive, Whitehouse Station, New Jersey, 08889-0100, U.S.A. (hereinafter referred to as "MERCK");

WITNESSETH:

WHEREAS, MERCK and SURMODICS have entered into an Exclusive License and Research Collaboration Agreement effective as of the date hereof (the "License Agreement") relating to a grant of a license from SURMODICS to MERCK; and

WHEREAS, as part of the License Agreement, MERCK desires to purchase, and SURMODICS desires to supply, MERCK and its Affiliates (as herein after defined) with Product (as hereinafter defined) in the Territory (as hereinafter defined) pursuant to the terms set forth herein.

NOW, THEREFORE, in consideration of the covenants herein contained, the parties hereto agree as follows:

1. DEFINITIONS

References to "Articles", "Sections" and "subsections" in this Agreement shall be to Articles, Sections and subsections respectively, of this Agreement unless otherwise specifically provided. Capitalized terms used but not defined herein shall have the meanings set forth in the License Agreement. As used in this Agreement the following terms, whether used in the singular or the plural, shall have the meanings set forth in this Article:

- 1.1 The term "Affiliate" shall mean with respect to any party, (a) any other Person of which [*] or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, general partnership interest of such other Person are owned, controlled, or held, directly or indirectly by, or under common ownership or control with, such party; or (b) any other Person that, directly or indirectly, owns, controls, or holds [*] (or the maximum ownership interest permitted by law) or more of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of such party or is otherwise able to control the direction of such party.
- 1.2 The term "Calendar Year" shall mean any period during the Term commencing on January 1 and ending on December 31.

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- 1.3 The term “cGMP” shall mean current Good Manufacturing Practices, as defined in FDA rules and regulations [*] including, without limitation, the United States regulations set forth at 21 CFR Parts 210-211 (with respect to Product), and Part 820 (with respect to Tools), as appropriate and as the same may be amended from time to time, [*].
- 1.4 The term “Clinical Product” shall mean the I-vation Platform that incorporates a Compound as an active ingredient, or the Surgical Instrument, in each case for use in Clinical Trials, the Research Program or other non-commercial uses.
- 1.5 The term “Change Control Procedure” shall have the meaning set forth in Section 6.14.
- 1.6 The term “Compound” shall mean as the case may be, (i) a TA Compound (as defined in the License Agreement, (ii) a [*] (as defined in the License Agreement), or (iii) a Licensed Other [*] Compound (as defined in the License Agreement).
- 1.7 The term “Contract Manufacturers” shall mean the Third Party (as defined in the License Agreement) contract manufacturers listed in Schedule 1.12, as the same may be amended as provided in Section 2.4, with which SURMODICS (or any of its permitted successors or assigns) or any of its Affiliates contracts for the Manufacture of Product in order to fulfill SURMODICS’ obligations under this Agreement.
- 1.8 The term “Deliver”, “Delivered” or “Delivery” with respect to a Product shall mean, and shall take place upon, the transfer of possession of such Product to a carrier designated by MERCK, [*], the applicable Facility.
- 1.9 The term “Economic Cost” shall have the meaning set forth in Schedule 1.9.
- 1.10 The term “Expansion Plan” shall have the meaning set forth in Section 2.3.
- 1.11 The term “Extraction Tool” shall mean the surgical tool that is used to remove the Intravitreal Implant from the eye.
- 1.12 The term “Facility” or “Facilities” shall mean the site or sites of Manufacture of Materials or Product, which shall be, as applicable (i) SURMODICS’ facility located at Eden Prairie, Minnesota, (ii) any new SURMODICS facility that may be constructed [*] or (iii) SURMODICS’ Contract Manufacturers’ facilities, in each case which are described on Schedule 1.12 as the same may be amended from time to time.
- 1.13 The term “Firm Order” means a binding commitment in writing made by MERCK to purchase Product from SURMODICS in accordance with Section 3.3.
- 1.14 The term “First Commercial Sale” shall mean the first sale of Marketed Product for end use or consumption in the first country in the Territory after all required approvals, including Marketing Authorizations, have been granted by the Regulatory Authority of

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such country, excluding, however, any sale or other distribution for use in a Clinical Trial.

- 1.15 The term “Force Majeure” shall have the meaning given in Section 13.4.
- 1.16 The term “Insertion Tool” shall mean the surgical tool that is used to insert the Intravitreal Implant into the eye.
- 1.17 The term “Intravitreal Implant” shall mean [*]
- 1.18 The term “I-vation Platform” shall mean [*]
- 1.19 The term “JSC” shall have the meaning given in Section 2.7(a).
- 1.20 The term “Launch Period” shall mean [*]
- 1.21 The term “License Agreement” shall have the meaning assigned in the recitals hereto.
- 1.22 The term “Long Range Plan” shall have the meaning set forth in Section 3.4.
- 1.23 The term “Manufacture/Manufacturing/Manufactured” shall mean all operations involved in the receipt, incoming inspections, storage and handling of Materials and the manufacturing, formulating, Primary Packaging, Secondary Packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing), release, and preparing for shipping of Product; provided that in the event MERCK elects to manufacture all or part of Product, then such portion of the manufacturing process shall be excluded from the definition of “Manufacture”.
- 1.24 The term “Marketed Product” shall mean the I-vation Platform that incorporates a Compound as an active ingredient in final form or the Surgical Instruments, in each case after Secondary Packaging, in each case for commercial sale or distribution in the Territory by prescription, over-the-counter or any other method.
- 1.25 The term “Marketing Authorizations” shall mean all approvals and permits from the relevant Regulatory Authority necessary to market and sell a Marketed Product in any country (including without limitation, all applicable pricing and governmental reimbursement approvals even if not legally required to sell Marketed Product in a country in the Territory).
- 1.26 The term “Materials” shall mean all raw materials, including without limitation, excipients, Compounds, components, containers, labels and packaging materials necessary for the Manufacture of Product.
- 1.27 The term “Merck Materials” shall have the meaning set forth in Section 2.5.

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- 1.28 The term “Month” shall mean a calendar month.
- 1.29 The term “Primary Packaged Product” shall mean either (i) the I-variation Platform that incorporates a Compound as an active ingredient or (ii) the Surgical Instrument(s), in each case contained in a primary container. For purposes of this Agreement, “primary container” shall mean packaging that comes into contact with such I-variation Platform or Surgical Instrument.
- 1.30 The term “Primary Packaging” shall mean the process of converting the I-variation Platform that incorporates a Compound as an active ingredient or a Surgical Instrument into Primary Packaged Product.
- 1.31 The term “Product” shall mean Marketed Product or Clinical Product, as the case may be.
- 1.32 The term “Quality Agreement” shall have the meaning set forth in Section 6.14.
- 1.33 The term “Quarter” shall mean the respective periods of three (3) consecutive calendar Months ending on March 31, June 30, September 30 and December 31.
- 1.34 The term “Recoupment Fee” shall have the meaning set forth in Section 2.1(d).
- 1.35 The term “Regulatory Authority” shall mean any applicable government regulatory authority involved in granting approvals for the Manufacturing, marketing, reimbursement and/or pricing of a Product in the Territory, including, without limitation in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function, and the corresponding authorities of the European Union and Japan.
- 1.36 The term “Related Parties” shall mean MERCK, its Affiliates, distributors, and their respective sublicensees, as applicable.
- 1.37 The term “Safety Stock” shall have the meaning set forth in Section 3.4.
- 1.38 The term “Secondary Packaging” shall mean putting Primary Packaged Product into packaging and performing labeling as specified in the Specifications.
- 1.39 The term “Specifications” shall mean the mutually agreed specifications for Product to be set forth in Schedule 1.39 hereto, as the same may be amended in writing by mutual agreement of the Parties from time to time.
- 1.40 The term “Surgical Instrument” or “Surgical Instruments” shall mean the Extraction Tool and/or the Insertion Tool in final form after Secondary Packaging.
- 1.41 The term “Supply Price” shall have the meaning set forth in Section 4.1.
- 1.42 The term “SurModics Profit” shall have the meaning given in Schedule 1.9.
- 1.43 The term “Term” shall have the meaning set forth in Section 12.1

1.44 The term “Territory” shall mean all of the countries in the world, and their territories and possessions.

1.45 The term “Unit” shall mean one unit of Product.

1.46 The term “Research Program” shall mean the research and development undertaken by the Parties as set forth in Article 2 and Schedule 2.1 of the License Agreement.

2. **SUPPLY OF PRODUCT; JOINT SUPPLY COMMITTEE**

2.1 (a) Appointment. SURMODICS agrees to supply, and MERCK agrees to purchase from SURMODICS, Product in the Territory during the Term, subject to the terms and conditions herein. For the purposes of this Agreement, all references to MERCK’s Firm Orders for Product (both Clinical Product and Marketed Product) shall include the Firm Orders of its Related Parties. MERCK’s Related Parties may purchase Product directly from SURMODICS under this Agreement upon notification to SURMODICS of their agreement to be bound by the terms and conditions hereof; provided that any majority owned subsidiary of MERCK may do so without such notification.

(b) Exclusivity. [*] MERCK shall purchase exclusively from SURMODICS, and SURMODICS shall supply, all of MERCK’s and its Related Parties’ requirements of Product in the Territory during the Term, subject to the terms and conditions herein.

(c) Alternate Supplier. MERCK may, upon [*] written notice to SURMODICS, terminate its obligation to exclusively purchase all Product(s) from SURMODICS any time following the Effective Date. [*] “Alternate Supplier” means a source of supply that has the capability to supply Product [*] (the “Alternate Supplier”).

(d) Recoupment of Capital Investment. If, anytime prior to or within [*] following the date of First Commercial Sale of the first Marketed Product, MERCK establishes an Alternate Supplier pursuant to Section 2.1(c) [*]

2.2 Shortage of Supply. In the event that at any time SURMODICS foresees that it will be unable to Manufacture in whole or in part an ordered or forecasted quantity of Product for any reason other than a shortage of Merck Materials, including as a result of Force Majeure, SURMODICS shall notify MERCK of such inability as soon as possible, giving the reasons therefore and the date such inability is expected to end, the quantities of Product available during such period and the proposed amount of the Materials and/or resources allocated to MERCK in the event such inability is caused by a shortage of Materials and/or resources required for the Manufacture of Product. [*]

2.3 Capital Investment and Capacity Expansion. The Parties acknowledge that SURMODICS will be making significant capital investments (the “Capital Investment”) in its Facilities in order to fulfill its obligations under this Agreement. An estimate of the

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expected Capital Investment is described in Schedule 2.3 hereto. The actual amount of the Capital Investment shall be determined by SURMODICS no later than [*] The Capital Investment shall be determined by SURMODICS in a manner consistent with SURMODICS' methodology for preparing the estimated Capital Investment set forth in Schedule 2.3 [*] and shall be supported by reasonable documentation. [*] SURMODICS shall use its Commercially Reasonable Efforts to acquire additional capacity for the Manufacture of MERCK's forecasted requirements of Marketed Product as set forth in the Research Program. Such actions may include, in SURMODICS' reasonable judgment, [*] SURMODICS shall use its Commercially Reasonable Efforts to minimize the Capital Investment.

- 2.4 Subcontracting. SURMODICS may not subcontract its obligations under this Agreement to any third party without MERCK's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. MERCK hereby acknowledges the third party Contract Manufacturers listed on Schedule 1.12 [*]. Schedule 1.12 shall be amended from time to time to include third party subcontractors consented to by MERCK.
- 2.5 Procurement of Materials. MERCK shall be responsible for the supply of the [*] (collectively, "Merck Compounds"). SURMODICS shall be responsible for the procurement of TA Compound and all other Materials. Notwithstanding the foregoing, MERCK shall have the option, with prior written notice to SURMODICS, to either manufacture or purchase any or all of the Materials (all such Materials shall be referred to herein as the "Merck Materials") and to supply Merck Materials to SURMODICS. The supply price for Merck Compounds and Merck Materials shall be mutually agreed upon by the Parties in good faith. With respect to the supply of the Merck Compounds and Merck Materials (in the event MERCK exercises its option to supply such MERCK Materials set forth above) to SURMODICS, the provisions set forth in Sections 2.2, 3.1 through Section 3.3, 3.5, and 4.2 through 4.5 shall apply to and shall be binding on MERCK, mutatis mutandis, except that (i) Merck Compounds and Merck Materials shall be delivered to SURMODICS [*], site of manufacture of Merck Materials, or such other location as mutually agreed upon by the Parties, and (ii) any payment due to MERCK shall be made by SURMODICS by crediting MERCK's account within [*] after its receipt of MERCK's invoice; provided, however, if within [*] of such payment becoming due to MERCK there is no sum owed by MERCK to SURMODICS to which such credit may be applied, SURMODICS shall pay such amount to MERCK.
- 2.6 Scale Up. In order to facilitate the Manufacture of Marketed Product, SURMODICS agrees to accomplish, at its expense and with MERCK's input and to MERCK's reasonable satisfaction, the Manufacturing activities set forth in Schedule 2.6, within the time frames specified therein.[*]
- 2.7 Joint Supply Committee. The Parties hereby establish a committee to facilitate the supply of Product as follows:

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

(a) Composition of the Joint Supply Committee. The commercialization scale-up contemplated in Schedule 2.6 and the supply activities under this Agreement shall be conducted under the direction of a joint supply committee (the “JSC”) which shall be comprised of [*] Each Party may change its representatives to the JSC from time to time, in its sole discretion, effective upon providing written notice to the other Party of such change. These representatives shall have appropriate manufacturing credentials, experience and knowledge, and ongoing familiarity with the commercialization scale-up and supply activities contemplated by this Agreement. Additional representatives or consultants may from time to time, by mutual consent of the Parties, be invited to attend JSC meetings, subject to such representative’s or consultant’s written agreement to comply with the requirements of Section 10.1. [*] Each Party shall bear its own expenses related to the attendance of such meetings by its representatives.

(b) Scope of JSC Oversight. The JSC’s oversight responsibilities shall be limited to the activities in this Agreement including those specified in Schedule 2.6. Within such scope, the JSC shall serve as a forum for:

- (i) [*]
- (ii) [*]
- (iii) [*]
- (iv) [*]
- (v) [*]
- (vi) [*]
- (vii) [*]
- (viii) [*] and
- (ix) [*]

(c) Decision-Making. [*]

(d) Meetings. The JSC shall meet in accordance with a schedule established by mutual written agreement of the Parties, with the location for such meetings alternating between SURMODICS and MERCK facilities (or such other location as may be determined by the JSC). Alternatively, the JSC may meet by means of teleconference, videoconference or other similar communications equipment.

(e) Termination of the JSC. All of the JSC’s functions and duties shall terminate upon the expiration or earlier termination of this Agreement.

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3. FORECASTS AND ORDERS

- 3.1 Clinical Product. Until the receipt of Marketing Authorizations, SURMODICS and MERCK shall from time to time meet and confer to discuss in good faith the quantity of Clinical Product MERCK desires to order under this Agreement and SURMODICS shall advise MERCK on the time required to produce and Deliver such quantities. Consistent with such discussions, the JSC shall provide SURMODICS with a forecast of MERCK's requirements for Clinical Product via the Research Plan or as may otherwise be communicated to SURMODICS through the JSC. MERCK shall submit Firm Orders to SURMODICS for such quantity of Clinical Product as is consistent with the discussions of the Parties and the forecast provided by the JSC, and SURMODICS shall Manufacture and Deliver such quantity of Clinical Product to MERCK under this Agreement.
- 3.2 [*] Forecast. In order to assist SURMODICS in its production planning, no later than [*] prior to the date of the anticipated First Commercial Sale, MERCK will provide SURMODICS with a written forecast of MERCK's [*] requirements of Marketed Products for the [*] following such First Commercial Sale. Changes to this initial forecast shall be made as they occur. Beginning at least [*] before the initial delivery of Marketed Product to MERCK pursuant to Firm Orders, and [*] thereafter, MERCK shall submit to SURMODICS its updated forecast for the next [*]. It is understood and agreed that estimates shall not constitute commitments to purchase Marketed Product or Firm Orders.
- 3.3 Firm Orders.
- (a) At least [*] prior to the beginning of each Month during the Term, MERCK shall place an order (a "Firm Order") for its requirements of Product for such Month. Each Firm Order shall specify the quantity of Product ordered, the required Delivery date and the shipping address. Each Firm Order for Marketed Product shall [*].
 - (b) Should MERCK request SURMODICS to supply Product in excess of MERCK's most recent estimate of its requirements, SURMODICS shall use its Commercially Reasonable Efforts to meet MERCK's request.
 - (c) [*]
 - (d) SURMODICS shall satisfy each Firm Order on or before the Delivery date specified in such Firm Order by MERCK, provided that such Delivery date is at least [*] after the date of the Firm Order. No Delivery shall be made more than [*] in advance of the date specified for Delivery in a Firm Order without MERCK's approval. The site(s) of Manufacture shall be indicated on documents accompanying each shipment of Product.

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(e) A Firm Order shall be made on such form of purchase order or document as MERCK may specify from time to time in writing (which may include electronic ordering), subject to Section 4.6; provided that the terms and conditions of this Agreement shall be controlling over the terms and conditions contained in any Firm Order. Any term or condition of such Firm Order that is different from or contrary to the terms and conditions of this Agreement shall be void.

3.4 Long Range Forecast. In addition to the rolling [*] forecast, no later than [*] prior to the anticipated date of the First Commercial Sale, and thereafter, by [*] of each Calendar Year, MERCK shall provide SURMODICS with a long range plan containing a non-binding estimate of annual requirements of Product for the following [*] (each a "Long Range Plan"). If at any time, a Long Range Plan reasonably suggests any supply issue, particularly as it relates to production capacity, the Parties shall discuss how to address the potential shortage.

3.5 Safety Stock

(a) On or before the anticipated date of the First Commercial Sale and thereafter during the Term, SURMODICS shall at its own cost and expense maintain an amount of inventory of Marketed Product equal to MERCK's requirements of such Marketed Product for commercial sale for [*] (the "Safety Stock"); provided, however, that if SURMODICS draws upon the Safety Stock and is unable to Manufacture additional Safety Stock due to a shortage of Merck Materials or Merck Compounds, SURMODICS shall be relieved of its obligation to maintain the Safety Stock until such time as MERCK begins supplying the Merck Materials or Merck Compounds in sufficient quantities for SURMODICS to Manufacture and maintain the Safety Stock as required hereunder.

(b) The Safety Stock shall be maintained for the sole benefit of MERCK and shall not be subject to allocation, and shall be stored at a secure Facility in compliance with cGMP, separate from the Facility where the Marketed Product is Manufactured. SURMODICS shall rotate the Safety Stock on a "First Expiry-First Out" basis for routine fulfillment of Firm Orders. MERCK shall have the right to reduce or eliminate the Safety Stock at any time by written notice to SURMODICS and, in such case, MERCK's obligation to purchase the Safety Stock under Section 12.9 of this Agreement shall be reduced or eliminated.

(c) In the event SURMODICS is not able to Manufacture any Firm Orders for Marketed Product for any reason, SURMODICS shall draw upon the Safety Stock to make up for any shortfall it is not able to Manufacture. Within [*] after the end of each Quarter, SURMODICS shall deliver a report to MERCK describing the quantities of the Safety Stock remaining as of the end of such Quarter.

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3.6 Shortage of Merck Materials. If SURMODICS is unable to Manufacture in whole or in part any ordered or forecasted quantity of Product due to a shortage of Merck Compounds or Merck Materials, (i) SURMODICS shall be excused from its supply obligations under this Agreement, except as to Safety Stock, to the extent of the shortage in the Merck Compound or Merck Materials, and (ii) the date on which SURMODICS is required to deliver the affected quantity of Product shall be extended by a period equal to the length of the delay in SURMODICS' receipt of the Merck Compounds and/or Merck Materials plus a reasonable time to resume production.

4. PRICE; PAYMENT AND TERMS OF SALE

4.1 Price.

(a) Supply Price. The supply price (the "Supply Price") payable by MERCK to SURMODICS for Product Delivered hereunder, shall be at SURMODICS' Economic Cost plus, [*] a reasonable and customary profit to SurModics equal to SurModics Profit and shipping costs payable by MERCK in accordance with the Delivery terms set forth in Section 4.4 below.

(b) [*]

(i) [*]

(ii) [*]

(iii) [*]

(c) Productivity Improvements. SURMODICS shall use its Commercially Reasonable Efforts with respect to managing the Economic Cost associated with the Manufacture and supply of Product hereunder. [*]

4.2 Payment. Payment of the Supply Price for Product Delivered to MERCK shall be made by MERCK in United States dollars, free and clear of any reduction, charges, fees or withholding of any nature unless acknowledged by SURMODICS in writing, within [*] after the date of invoice, which invoice shall be issued by SURMODICS on or after the Delivery date, and shall be paid by bank wire transfer to a bank account designated in writing by SURMODICS from time to time.

4.3 [*]

4.4 Delivery. SURMODICS shall tender Product purchased by MERCK for Delivery [*] the applicable [*], addressed to the shipping address specified in the Firm Order. MERCK shall select transportation modes and carriers and shall provide SURMODICS with standard shipping instructions at least [*] prior to the first requested shipping date hereunder; thereafter, MERCK may modify such shipping instructions in accordance with the timing set forth in Section 3.3(c).

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- 4.5 Title and Risk of Loss. Title to the Product sold hereunder shall pass to MERCK, and SURMODICS' liability as to Delivery thereof shall cease upon Delivery, whereupon MERCK shall assume all risk of loss or damage.
- 4.6 Terms of Sale. The terms and conditions of this Agreement shall be controlling over any inconsistent terms or conditions included in any Firm Order or any other sales acknowledgment or document. No provision of MERCK's purchase order forms which may impose different conditions than those herein referenced upon SURMODICS, MERCK or their respective Affiliates shall be of any force or effect unless expressly agreed to in writing by SURMODICS.
- 4.7 Dating. The Parties acknowledge and agree that the shelf life of Product supplied under this Agreement will depend on various factors, including, for example, the Product's Specifications and the Compound incorporated into such Product. [*]

5. **WARRANTY AND LIMITATIONS**

- 5.1 SURMODICS Warranty. SURMODICS represents and warrants that all Product shall, at the time of Delivery, be Manufactured [*]
- 5.2 Warranty Claims. MERCK shall conduct inspections of each shipment of Product and may reject all or any portion of such shipment that MERCK reasonably believes did not, at the time of Delivery, meet one or more of the warranties specified in Section 5.1(i), 5.1(ii) or 5.1(iii) (such shipment quantities are hereinafter referred to as the "Allegedly Non-Conforming Products", and, if determined not to have met such warranties, "Non-Conforming Products") by giving written notice to SURMODICS [*] after receipt of shipment of the Allegedly Non-Conforming Products.] Such notice shall identify in reasonable detail the nature of the nonconformity. If MERCK fails to provide SURMODICS with written notice of Allegedly Non-Conforming Products within such [*], MERCK will be deemed to have accepted the Products. [*]
- (a) [*]
- (b) [*]
- 5.3 Disposition of Non-Conforming Product. Any Products which are found to be Non-Conforming Products under Section 5.2 and which are in MERCK's control shall, [*] either be returned to SURMODICS at SURMODICS' expense, or shall be destroyed pursuant to SURMODICS' instructions and with MERCK's approval, which approval shall not be unreasonably withheld, at SURMODICS' expense.
- 5.4 MERCK Warranty. MERCK represents and warrants that the Merck Compounds and all Merck Materials shall, at the time of Delivery, be produced [*]

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5.5 No Debarment. SURMODICS hereby represents, warrants and covenants that it will not, and has not, employed or otherwise used in any capacity the services of any person debarred under Section 21 U.S.C. 335a in performing any portion of the Manufacture of Product and MERCK hereby represents, warrants and covenants that it will not, and has not, employed or otherwise used in any capacity the services of any person debarred under Section 21 U.S.C. 335a in performing any portion of the manufacture of Merck Compounds or Merck Materials.

5.6 Disclaimer. THE WARRANTIES CONTAINED IN ARTICLE 5 ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES HEREUNDER, AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES.

6 QUALITY

6.1 General Obligations. (a) Compliance. SURMODICS shall Manufacture and supply Product in accordance with the Specifications, in accordance with applicable laws, regulations and Regulatory Authority requirements, including but not limited to, all drug listing requirements, and in accordance with cGMPs. (b) Labeling. MERCK shall be responsible for (and shall provide to SURMODICS in writing) the content of all labels, packaging and package inserts for Marketed Product and for ensuring that such content complies with the Marketing Authorizations and with all applicable laws, regulations and Regulatory Authority requirements for each country where Marketed Product is marketed. [*]

6.2 [*]

6.3 Facilities; Audits.

- (a) SURMODICS shall, at its own cost and expense, ensure that the Facilities are in a qualified and validated state appropriate for inclusion as manufacturing sites for Product as required by the applicable Regulatory Authority at the time the first application for Marketing Authorization is submitted by MERCK. SURMODICS shall (or shall cause its Contract Manufacturers to), at its (or its Contract Manufacturer's own) cost and expense, maintain the qualification and validation status of the Facilities during the Term.
- (b) SURMODICS shall Manufacture (or cause to be Manufactured) all Product supplied hereunder at the Facilities. Manufacturing of Product may not be relocated without MERCK's prior written consent, which consent shall not be unreasonably withheld or delayed. Any such relocation of the Manufacturing of Product shall comply with cGMPs and all applicable laws, regulations and

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Regulatory Authority requirements and shall be made in accordance with the Change Control Procedure.

- (c) SURMODICS shall and shall cause its Contract Manufacturers to permit one or more qualified technical specialists from MERCK, upon at [*] notice and for reasonable duration ([*]) during regular business hours to visit the Facilities, or any other facility which is proposed to be used to Manufacture Product, for purposes of auditing compliance by SURMODICS and its Contract Manufacturers in the Manufacture of Product with applicable laws, regulations and Regulatory Authority requirements, including cGMPs, and with the Quality Agreement; provided, however, that such audits shall be conducted not more than [*] in [*] All information obtained by MERCK in any such inspection or audit, including without limitation the findings and results related thereto, shall be the confidential information of SURMODICS provided, however, that nothing contained herein shall be construed as restricting the right of either party to take action that it deems in good faith to be required by applicable law or regulation. [*] MERCK shall have the right to review all relevant documentation pertinent to such corrective actions implemented by SURMODICS or its Contract Manufacturer.
- 6.4 Maintenance; Validation. SURMODICS agrees, at its expense, to operate and maintain (or to cause its applicable Contract Manufacturer to operate and maintain) the Facilities and all equipment used, directly or indirectly, to Manufacture Product in accordance with cGMPs and all applicable laws and regulations and Regulatory Authority requirements and to maintain (or cause to be maintained) said Facilities and equipment in an acceptable state of repair and operating efficiency so as to meet the Specifications and comply with the SURMODICS Know-How. SURMODICS shall be responsible for validating (or causing its Contract Manufacturer to validate) the equipment (including without limitation conducting installation, operational and performance qualification), production, cleaning, packaging, processing and any other appropriate steps performed at the Facilities. Validation procedures used by SURMODICS (or its Contract Manufacturers) as of the Effective Date may continue to be used by SURMODICS (or its Contract Manufacturers); [*]
- 6.5 Costs of Compliance. Any costs or expenses related to bringing a Facility or any equipment needed to Manufacture Product into compliance with any applicable Regulatory Authority requirements at any time shall be borne exclusively by SURMODICS or its Contract Manufacturer, as the case may be.
- 6.6 Certificate of Analysis. SURMODICS shall provide MERCK with certificates of analysis related to Product for each batch released for Delivery hereunder. These certificates will document that each batch of Product tendered for Delivery to MERCK conforms to the Specifications. These certificates shall include the date of Manufacture and either a retest date or expiry date for Product, as appropriate. A copy of each certificate shall be included with each batch of Product Delivered to MERCK, and one

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copy shall be faxed at the same time to the MERCK representative specified in the Quality Agreement. SURMODICS shall also provide MERCK with (i) Regulatory Authority certification, for those countries in which the applicable Regulatory Authority is in the practice of requiring any such certifications, and (ii) any technical or analytical support, including transfer of test methods, as reasonably necessary for MERCK or its Related Parties to release Product in satisfaction of applicable Regulatory Authority requirements.

- 6.7 Quality Control Testing. SURMODICS shall perform, at its quality control laboratories, such quality control tests as are indicated in the Specifications, in accordance with the test methods and procedures set forth or referred to therein or in the Quality Agreement. SURMODICS shall make the results of its quality control tests available to MERCK on or before the date of Delivery of the corresponding batches of Product. No production batch of Product shall be released for Delivery unless SURMODICS' tests show the Product to meet the standards set forth in the Specifications. Should any production batch fail to meet the standards set forth in the Specifications, SURMODICS shall promptly investigate the cause of such failure and promptly provide MERCK with a written report summarizing the results of SURMODICS' investigations, including the root cause of the failure and the corrective actions and follow-up preventative actions to be done to remedy the failure. [*] MERCK shall perform, at MERCK's expense, such confirmatory testing of Product released for Delivery to MERCK as MERCK may deem appropriate, which may include, but is not limited to, the recommended procedures set forth in the Specifications. MERCK shall advise SURMODICS of any failure of such Product to meet the standards set forth in the Specifications without undue delay.
- 6.8 Product Release. MERCK is responsible for final release of each lot of Product for sale within the Territory in accordance with MERCK's standard practices, the Marketing Authorizations and all applicable laws, regulations and Regulatory Authority requirements. SURMODICS is responsible for providing a copy of those Manufacturing records, including but not limited to a certificate of compliance, certificate of analysis, batch records and other documents, if any, as may be further specified in the Quality Agreement, for each lot of Product Manufactured in support of MERCK's responsibility for final release decision.
- 6.9 Reference Samples. SURMODICS shall supply MERCK, upon request, with reasonable quantities of reference samples relating to Product, at the cost of SURMODICS, in order to facilitate MERCK's confirmatory testing.
- 6.10 Retention of Samples. SURMODICS, at its own expense, is responsible for retaining representative samples of each lot of Product Manufactured and starting materials used in the Manufacture of each lot of Product. The quantity of retention samples shall be at least [*] times the amount of Product or starting materials required to perform quality control release testing or such other quantity as may be set forth in the Quality Agreement. Such amounts shall be stored and retained for [*] After such [*] period as the case may be, if requested by MERCK, SURMODICS shall make arrangements for

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contracted storage of such Product samples, as agreed upon by MERCK, at MERCK's expense. At any time following such [*] (or longer) period, if SURMODICS decides that it will no longer store such samples, it shall provide no less than [*] written notice to MERCK, during which time MERCK may instruct SURMODICS to either ship such samples to MERCK or destroy such samples. SURMODICS shall comply with such instructions from MERCK, provided that MERCK shall reimburse SURMODICS its reasonable expenses incurred in shipping or destroying such samples. Retained samples of Product shall be visually examined at least annually. SURMODICS shall promptly notify MERCK of any observed abnormality.

- 6.11 Stability Testing. SURMODICS shall, at its own expense, perform an on-going program of annual stability testing, in accordance with a protocol approved by MERCK, such approval not to be unreasonably withheld or delayed, on samples from [*] production batches of Product initially, and at least [*] batch of Product [*] thereafter for each packaging type. Such stability testing shall be stability indicating. In the event that SURMODICS detects any instability and/or degradant in excess of approved limits in connection with such testing, SURMODICS shall notify MERCK within [*] of such detection. SURMODICS shall specifically incorporate such additional testing and controls (e.g., storage condition changes) as MERCK may reasonably specify with respect to such instability and/or degradant. In addition, SURMODICS shall place one batch of Product on stability following the implementation of any change described in Section 6.2. Furthermore, any batch Manufactured with one or more significant deviations should be assessed for possible inclusion in stability studies.
- 6.12 Annual Review. SURMODICS agrees to implement and perform, at its own expense, an Annual Review Program for Product including, but not limited to, a review of production related and quality control testing related atypical investigations.
- 6.13 Cross Contamination. Except as set forth on Schedule 6.13, SURMODICS hereby declares that as of the date of execution of this Agreement neither it nor its Contract Manufacturers is producing, packaging, labeling, warehousing, quality control testing (including in-process, release and stability testing), releasing or shipping any chemical entity classified as [*] In the event that SURMODICS or its Contract Manufacturers intends, during the course of this Agreement, to produce, package, label, warehouse, quality control test (including in-process, release and stability testing), release or ship any chemical entity belonging to the classes of products listed above, SURMODICS shall promptly notify MERCK in writing of its or its Contract Manufacturers' intention to do so in order to allow MERCK to consider any potential questions relating to cross-contamination or Regulatory Authority requirements. SURMODICS acknowledges that MERCK has not had the opportunity to fully assess the matters disclosed on Schedule 6.13 and that further measures (procedural or segregation) beyond those described in Schedule 6.13 may be necessary to address potential cross-contamination issues relating to the I-vation Products. In the event MERCK identifies a potential problem of cross-contamination or with Regulatory Authority requirements that would prohibit the activity, [*]
- 6.14 Quality Agreement. As soon as practicable after the Effective Date but in no event more than [*] thereafter, the Parties shall negotiate and execute a supplemental Quality

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Agreement (the “Quality Agreement”), consistent with the terms of this Agreement, which shall provide for each Party’s respective compliance responsibilities associated with the Manufacture of Product, including but not limited to a mutually agreeable change control request and approval procedure (the “Change Control Procedure”). If and when MERCK exercises its option to supply Merck Materials under Section 2.5, the Quality Agreement and Change Control Procedure shall be amended by the Parties to provide for each party’s respective compliance responsibilities associated with the manufacture, formulation, handling, storage, testing and other operations relating to the supply and use of Merck Materials. In the event of any inconsistency between this Agreement and the Quality Agreement, the terms of this Agreement shall govern unless otherwise specifically stated in the Quality Agreement or agreed in writing by the Parties.

7. RECORDS RETENTION

- 7.1 All batch records, quality control records, batch release records, product stability records, deviation reports, and master production and control records relating to the Manufacture of each batch of Product shall be retained by SURMODICS or its Contract Manufacturers for a period of not less than [*] Thereafter, SURMODICS shall notify MERCK of any intention to destroy such records and shall afford MERCK the opportunity to obtain such records at MERCK’s expense, whether from SURMODICS or its Contract Manufacturers. SURMODICS shall provide (or cause its Contract Manufacturers to provide) MERCK with complete and accurate copies of the foregoing documents for each production batch, upon MERCK’s request and at MERCK’s expense.

8 REGULATORY MATTERS

- 8.1 Recalls.
- (a) In the event that Marketed Product is recalled or withdrawn, SURMODICS shall fully cooperate with MERCK, [*], in connection with such recall or withdrawal. [*]
- (b) [*]
- 8.2 Safety. SURMODICS shall promptly (and, in any event, within [*]) notify MERCK of any information of which it becomes aware concerning Product supplied to MERCK which may affect the safety or efficacy and continued marketing of the Product. Any such notification will include all related information in reasonable detail. Upon such notification, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either party to make a timely report of such matter to any Regulatory Authority or take other action that it deems to be appropriate or required by applicable law or regulation. Each party will notify the other promptly of any health hazards with respect to Product which may impact employees involved in the Manufacture of Product.

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- 8.3 Regulatory Authority Inspection. SURMODICS hereby agrees to advise MERCK promptly (and, in any event, within [*]) of any proposed or unannounced visit or inspection by any authorized agent of a governmental authority, including any Regulatory Authority or any environmental regulatory authority, to a Facility (whether owned by SURMODICS, an Affiliate or a Contract Manufacturer) where such visit or inspection is specifically related to the Product or its Manufacture (a “Product-Related Inspection”). SURMODICS agrees to permit (and SURMODICS shall cause its Contract Manufacturers to permit), to the extent reasonably practical, one or more qualified representative(s) of MERCK to be present during a Product-Related Inspection if requested by MERCK. If MERCK is not present during a Product-Related Inspection, SURMODICS shall promptly provide a summary report of the results of the Product-Related inspection to MERCK in English. SURMODICS shall promptly (and, in any event, within [*]) furnish MERCK English summaries of all reports, documents or correspondence with respect to any Regulatory Authority requests or inspections of a Facility if such reports, documents or correspondence are related to the Product or its Manufacture, as well as a copy of each such report, document or correspondence in English. The Parties will cooperate in the development and review of responses that are required to be submitted to any Regulatory Authority relating to the Manufacture of Product prior to submission to the Regulatory Authority. Nothing contained within this Section 8.3 shall restrict the right of either Party to make a timely report of such matter to any Regulatory Agency or take other action that it deems to be appropriate or required by applicable law or regulation. SURMODICS shall promptly notify MERCK of any Regulatory Authority request for samples of Product or Manufacturing batch records and will not provide such material until such notification is made to MERCK.
- 8.4 Complaints and Adverse Events. SURMODICS hereby agrees to advise MERCK promptly (and, in any event, within [*]) of any complaint information (including adverse event information) SURMODICS receives relating to Product. SURMODICS will assist MERCK in investigating and resolving all complaints and adverse events related to the Manufacturing of the Product. MERCK will be responsible for evaluating and investigating complaints and for communicating to any Regulatory Authorities regarding Product complaints or adverse events. SURMODICS will take any corrective actions agreed to by the Parties to avoid future occurrences of Product complaints or adverse events related to the Manufacturing of the Product.

9 INDEMNITY; LIMITATION OF LIABILITY

- 9.1 Indemnification by SURMODICS. Subject to Section 9.4, SURMODICS agrees to indemnify, defend and hold harmless MERCK, its Affiliates and their respective directors, officers, employees and agents from and against any liabilities, losses, costs, damages, fees or expenses arising out of any [*] (“Losses”) relating to or resulting from [*]
- 9.2 Indemnification by MERCK. Subject to Section 9.4, MERCK agrees to indemnify, defend and hold harmless SURMODICS, its Affiliates and their respective directors,

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officers, employees and agents from and against any Losses relating to or resulting from [*]

9.3 [*] A person or entity entitled to indemnification under this Article 9 (an “Indemnified Party”) shall give prompt written notification to the party from whom indemnification is sought (the “Indemnifying Party”) of the commencement of any action, suit or proceeding relating to a [*] claim for which indemnification may be sought or, if earlier, [*] (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a [*] claim as provided in this Section 9.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within [*] after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such [*] claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party.

9.4 Limitations on Indemnification and Liability.

[*]

10. CONFIDENTIALITY AND PUBLIC ANNOUNCEMENTS

10.1 Nondisclosure Obligation. The provisions contained in Article 4 “Confidentiality and Publication” of the License Agreement are hereby incorporated by reference as if set forth herein in full.

11. ARBITRATION/GOVERNING LAW

11.1 Governing Law; Disputes. This Agreement shall be interpreted by and construed according to the substantive laws of the State of New York, USA, without reference to any rules of conflict of laws or renvoi. The U.N. Convention on International Sales of Goods shall not apply. In the event of any controversy or claim arising out of or relating

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to this Agreement or breach thereof, the dispute resolution and arbitration provisions of Section 11.6 of the License Agreement shall apply.

11.2 Remedies Cumulative. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available at law or in equity.

12. TERM AND TERMINATION

12.1 Term. This Agreement shall be effective as of the Effective Date and shall continue in effect, unless earlier terminated as provided in this Article 12 (the "Term") until [*] (as defined in the License Agreement) in the Territory; provided that, MERCK may, in its sole discretion, extend the Term for an additional [*] period by providing SURMODICS with written notice no less than [*] prior to the expiration of the initial Term.

12.2 Mutual Agreement. This Agreement may be terminated by written agreement of the Parties.

12.3 Termination by Either Party. This Agreement may be terminated with written notice by either party to the other at any time during the term of this Agreement:

- (a) if the other party is in breach of its material obligations hereunder (except by a Force Majeure cause pursuant to Section 13.4) and has not cured such breach within [*] after written notice requesting cure of the breach has been given; provided, however, that in the event of a good faith dispute with respect to the existence of a material breach, the [*] cure period shall be tolled until such time as the dispute is resolved pursuant to Section 11.1 hereof; or,
- (b) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by the other party or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party; provided, however, in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the party consents to the involuntary bankruptcy or such proceeding is not dismissed within [*] of the filing thereof.

12.4 Termination by MERCK. This Agreement may be terminated by MERCK at its sole discretion, in whole or in part, at any time following the Effective Date upon [*] written notice to SURMODICS.

12.5 Termination by SURMODICS. This Agreement may be terminated by SURMODICS at its sole discretion [*].

12.6 Termination of License Agreement. [*]

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- 12.7 Payment of Outstanding Debts. Upon expiration or termination of this Agreement for whatever reason, either party shall settle all outstanding invoices or monies owed to the other party or its Affiliates pursuant to their stated terms; provided however, that in the event the termination is the result of a breach by a party, all amounts owed to the other party shall become immediately due and payable.
- 12.8 Return of Information. Unless otherwise permitted under this Agreement or the License Agreement, within [*] subsequent to the expiration or termination of this Agreement, either party shall return to the other party all Information received from the other party, including all copies thereof, and forward to the other party all documents or materials created from such Information; provided, however, that each party shall have the right to retain one copy of Information in its confidential files to the extent retention of such Information is required by applicable laws and regulations.
- 12.9 Effects of Termination.
- (a) [*]
 - (b) [*]
 - (c) [*]
 - (d) [*]
- 12.10 Surviving Clause. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination. In addition to those Sections which by their terms are intended to survive termination of this Agreement, [*]
13. **MISCELLANEOUS PROVISIONS**
- 13.1 Binding Effect; Assignment. This Agreement shall inure to the benefit of and be binding upon each of the Parties hereto and their respective successors and permitted assigns. Neither party may assign, transfer or otherwise dispose of this Agreement or any obligation with respect thereto, to any party without the prior written consent of the other party, such consent not to be unreasonably withheld, except that either party may, without the other party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate (other than an Affiliate that was created to facilitate a change of control) of the assigning party.
- 13.2 Cooperation. Each party agrees to execute such further papers, agreements, documents, instruments and the like as may be necessary or desirable to effect the purpose of this Agreement and to carry out its provisions.

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13.3 Entire Agreement. This Agreement, together with the License Agreement and the Quality Agreement, contain the entire agreement between the Parties with respect of the subject matter hereof and supersedes and cancels all previous agreements, negotiations, commitments and writings in respect of the subject matter hereof and may not be changed or modified in any manner, or released, discharged, abandoned, or otherwise terminated unless in writing and signed by the duly authorized officers and representatives of the Parties.

13.4 Force Majeure.

- (a) Neither party shall be liable for the failure or delay in performing any obligation under this Agreement (except for the payment of money) affecting MERCK, SURMODICS, its Affiliate or any Contract Manufacturer nor shall any party have the right to terminate this Agreement if and to the extent such failure or delay is due to any of the following causes beyond the reasonable control of the other party (collectively, "Force Majeure") (a) acts of God; (b) unusually severe weather, fire or explosion; (c) war, invasion, riot or other civil unrest; (d) governmental laws, orders, restrictions, actions, embargoes or blockades; (e) action by any Regulatory Authority (unrelated to the affected party's performance hereunder); (f) national or regional emergency; (g) strikes, lockouts, labor trouble or other industrial disturbances; (h) shortage of adequate fuel, power, Materials or transportation facilities; or (i) any other event which is beyond the reasonable control of the affected party; provided that the party affected shall promptly notify the other of the Force Majeure condition and shall exert all reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as reasonably possible.
- (b) During the duration of any Force Majeure, SURMODICS shall allocate Materials and/or resources required for the Manufacture of Product in the manner set forth in Section 2.2, subject to Section 3.6.
- (c) The requirements that all reasonable efforts be made to eliminate, cure or overcome a Force Majeure condition shall not require the settlement of strikes or labor controversies by acceding to the demands of the opposing party or parties.

13.5 Insurance. SURMODICS agrees to maintain, during the Term and for [*]

13.6 Headings. The Article and Section headings in this Agreement are solely for the convenience and reference of the Parties hereto and are not intended to be descriptive of the entire contents of, or to affect, any of the terms or provisions hereof or their interpretation.

13.7 No Agency. Nothing contained herein shall be deemed to establish or otherwise create a relationship of principal and agent between SURMODICS and MERCK, or MERCK and

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SURMODICS, it being understood that each of SURMODICS and MERCK is an independent contractor who cannot and shall not be deemed an agent of the other or its Affiliates for any purpose whatsoever. Neither SURMODICS nor any of its agents or employees shall have any right or authority to assume or create any obligation of any kind, whether express or implied, on behalf of MERCK or its Affiliates or have any authority to bind MERCK or its Affiliates in any way without the prior written approval of MERCK. Neither MERCK nor any of its agents or employees shall have any right or authority to assume or create any obligation of any kind, whether express or implied, on behalf of SURMODICS or its Affiliates or have any authority to bind SURMODICS or its Affiliates in any way without the prior written approval of SURMODICS.

- 13.8 Notice. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, to the intended recipient at its address set forth below or to such other business address as may have been furnished in writing by the intended recipient to the sender. Any such notice shall be deemed to have been given: (a) when delivered, if personally delivered or sent by facsimile on a business day (or if delivered or sent on a non-business day, then on the next business day); (b) on the business day after dispatch, if sent by nationally-recognized overnight courier; or (c) on the fifth (5th) business day following the date of mailing, if sent by mail. Any required notice shall be given in English.

Notice to SURMODICS shall be addressed to:

SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344
Attn: Chief Executive Officer
Facsimile: (952) 829-2743

With a copy to:

SurModics, Inc.
One Corporate Park
Suite 150, Irvine, CA 92606
Attention: President, Ophthalmology Division
Fax: (949) 387-7465

Notice to MERCK shall be addressed to:

Merck & Co., Inc.
Two Merck Drive
Whitehouse Station, New Jersey 08889-0100 U.S.A.
Attention: [*]
Facsimile:

with a copy to:

Merck & Co., Inc.
One Merck Drive
Whitehouse Station, New Jersey 08889-0100 U.S.A.
Attention: [*]
Facsimile: [*]

Either party may change its address by giving written notice to the other party.

- 13.9 Prevailing Language. The Agreement shall be prepared and executed in English and if translated into a language other than English for any purpose, the English version shall in all events prevail and be paramount in the event of any differences, questions or disputes concerning the meaning, form, validity, or interpretation of this Agreement.
- 13.10 Severability. In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the substantive rights of the Parties. The Parties shall in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.
- 13.11 Modification and Waiver. No amendment, modification or alteration of the terms of this Agreement shall be binding unless the same shall be in writing and duly executed by the Parties hereto, except that any of the terms or provisions of this Agreement may be waived in writing at any time by the party which is entitled to the benefits of such waived terms or provisions. No waiver of any of the provisions of this Agreement shall be deemed to or shall constitute a waiver of any other provision hereof (whether or not similar). No delay on the part of any party exercising any right, power or privilege hereunder shall operate as a waiver thereof.
- 13.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute one and the same agreement.

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

- 13.13 Waiver of Rule of Construction. Each party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting party shall not apply.
- 13.14 Successors and Assigns. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties hereto and their respective successors and permitted assigns.
- 13.15 Audit Rights. Upon the written request of MERCK and not more than [*], SURMODICS shall permit [*] to such of the records of SURMODICS as may be reasonably necessary to verify the accuracy of the Supply Price invoiced to MERCK hereunder for any year [*] prior to the date of such request. [*] of the date MERCK delivers to SURMODICS such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. [*] Upon the expiration of [*] following the end of any Calendar Year, the calculation of the Supply Price payable with respect to such Calendar Year shall be binding and conclusive upon MERCK, and SURMODICS shall be released from any liability or accountability with respect to the Supply Price charged for such year. MERCK shall treat all financial information subject to review under this Section 13.15 in accordance with the confidentiality and non-use provisions of Article 4 of the License Agreement, and [*] to enter into an acceptable confidentiality agreement with SURMODICS obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

SURMODICS, INC.

MERCK & CO., INC.

By: _____
Name:
Title:

By: _____
Name:
Title:

* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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SCHEDULE 1.39

Specifications

Current Research and Development Product Specifications

I. Clinical Supply of Product

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II. Primary Packaging of Product

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III. Secondary Packaging and Labeling of Product

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Schedule 1.39

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

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SCHEDULE 2.6

Scale-Up Activities

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Schedule 2.6

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Schedule 2.6

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Schedule 2.6

SCHEDULE 6.13

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

Schedule 6.13

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* Portions omitted pursuant to a request for confidential treatment and filed separately with the Securities and Exchange Commission.

**CERTIFICATION PURSUANT TO SECTION 302
OF SARBANES-OXLEY ACT OF 2002**

I, Bruce J Barclay, Chief Executive Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SurModics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 9, 2007

Signature: /s/ Bruce J Barclay
Bruce J Barclay
Chief Executive Officer

**CERTIFICATION PURSUANT TO SECTION 302
OF SARBANES-OXLEY ACT OF 2002**

I, Philip D. Ankeny, Chief Financial Officer, certify that:

1. I have reviewed this quarterly report on Form 10-Q of SurModics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 9, 2007

Signature: /s/ Philip D. Ankeny
Philip D. Ankeny
Chief Financial Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SurModics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2007, as filed with the Securities and Exchange Commission (the "Report"), I, Bruce J Barclay, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2007

/s/ Bruce J Barclay

Bruce J Barclay
Chief Executive Officer

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of SurModics, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2007, as filed with the Securities and Exchange Commission (the "Report"), I, Philip D. Ankeny, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2007

/s/ Philip D. Ankeny
Philip D. Ankeny
Chief Financial Officer